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, 2023

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.)**
101 Cambridgepark Drive Cambridge, Massachusetts	**02140**
(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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, was $463,030,964. 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 1, 2024 there were 151,009,462 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 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 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, manufacturing activities and related timing, expected benefits of our restructuring initiative and cost saving measures, 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 may be unable to realize the expected benefits from our restructuring and other cost reduction efforts.
- We are a commercial-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 VOWST and our product candidates, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We depend heavily on the commercial success of VOWST, which was only recently approved for marketing by the FDA and launched in the United States. There is no assurance that our commercialization efforts or those of our collaborators will be successful or that we will be able to generate collaboration profit at the levels or within the timing we expect.

- 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 VOWST, we are early in our development efforts of our product candidates and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop additional marketable drugs.
- VOWST and our product candidates are based on microbiome therapeutics, which is a novel 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.
- The 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 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 and product candidates 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 and 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 though VOWST has received FDA approval and even if any of our product candidates receive marketing approval, VOWST and such product candidates 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 or 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.

PART I

Item 1. Business

Overview

We are a commercial-stage microbiome therapeutics company focused on the development and commercialization of 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. Our first drug, VOWST™ (fecal microbiota spores, live-brpk), formerly called SER-109, was approved by the U.S. Food and Drug Administration, or FDA, on April 26, 2023, to prevent recurrence of *Clostridioides difficile* infection, or CDI, in patients 18 or older following antibacterial treatment for recurrent CDI. Our drug discovery and development pipeline includes other pre-clinical and clinical-stage assets. VOWST and our microbiome therapeutic candidates are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. We maintain a differentiated microbiome therapeutics drug discovery and development platform that includes good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality.

Our highest priority is the commercialization of VOWST in the United States, the first orally administered microbiome therapeutic approved by the FDA. We launched VOWST in the United States with our collaborator, Nestlé Health Science, or Nestlé, in June 2023.

We are also designing microbiome therapeutics optimized to decolonize pathogens and to modulate host function to both reduce and prevent infections and induce immune tolerance. 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, including pathogens that harbor antimicrobial resistance, or AMR.

In addition, we are evaluating SER-155 in a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HSCT, to prevent enteric-derived infections and resulting blood stream infections, as well as induce immune tolerance responses to reduce the incidence of graft-versus-host disease, or GvHD. In May 2023, we announced the Phase 1b cohort 1 results. Gastrointestinal microbiome data from the first 100 days of SER-155 Phase 1b open-label study cohort 1 showed the successful engraftment of SER-155 bacterial strains, and a substantial reduction in the cumulative incidence of pathogen domination as compared to a reference cohort of patients, a biomarker associated with the risk of serious enteric infections and resulting bloodstream infections, as well as GvHD in this patient population. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT. Enrollment in the placebo-controlled cohort 2 portion of the study is ongoing, and the cohort 2 data readout is anticipated in the third quarter of 2024.

We have progressed additional preclinical stage programs to evaluate whether microbiome therapeutics may reduce the incidence of infection in indications such as chronic liver disease, cancer neutropenia, solid organ transplant, and AMR infections more broadly in high-risk settings such as intensive care units. Additional efforts in the early-stage portfolio are focused on the SER-301 program in irritable bowel disease, or IBD, and programmatic objectives that are supported through a partnership with the Crohn's and Colitis Foundation, or CCF. These efforts aim to (i) confirm the functional phenotype and inflammatory state of patient subpopulations observed in our prior ulcerative colitis, or UC, clinical trials, and (ii) prioritize inflammatory targets and evaluate 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 prioritize future drug targets and to identify opportunities for combination therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform and knowledge base for the discovery and development of microbiome therapeutics, and maintain extensive proprietary know-how that may be used to support future research and development efforts. 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. This platform and knowledge base enables both identification of specific microbes and microbial metabolites/peptides that are associated with disease and the design of therapeutic consortia of bacteria optimized for specific pharmacological properties. In addition, we own a valuable intellectual property estate related to the development and manufacture of microbiome therapeutics.

In November 2023, we announced a restructuring plan, or the Restructuring Plan, to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while reducing costs and supporting longer-term business sustainability. The Restructuring Plan included (i) a reduction of our workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space. The Restructuring Plan was substantially implemented around the end of fiscal 2023. In connection with the Restructuring Plan, for the year ended December 31, 2023, we incurred approximately $5.6 million in restructuring costs, primarily related to the workforce reduction, of which $5.3 million are expected to result in cash expenditures, and the remaining $0.3 million relates to stock-based compensation expense associated with the acceleration of unvested equity awards. These costs were incurred in the fourth quarter of 2023. See Note 13, *Restructuring*, to our audited consolidated financial statements included elsewhere in this Annual Report. We expect to achieve annual cash savings of approximately $75.0 million to $85.0 million in 2024, of which approximately $35.0 million is expected to result from the reduction in workforce, and which excludes any one-time charges primarily associated with the workforce reduction.

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 the commercialization of VOWST in the United States and the completion of the SER-155 Phase 1b study. Additionally, we continue to advance our differentiated microbiome drug discovery, development and manufacturing platforms and capabilities.

Advancing our Programs

- ***Supporting the commercialization of VOWST in the United States.*** VOWST was approved by the FDA in April 2023 and is the first and only orally administered microbiome therapeutic to prevent the recurrence of CDI in patients 18 or older following antibacterial treatment for recurrent CDI. In close collaboration with Nestlé, we have scaled our healthcare provider education efforts, worked to create a positive customer experience with faster and higher conversion of enrollments to new patient starts, and continued to establish payer coverage. Since the FDA approval of VOWST, Nestlé commercial customer facing field teams have been promoting VOWST and generating healthcare provider demand, including significant presence at both IDWeek and the American College of Gastroenterology, or ACG, meetings in October 2023. Nestlé's 170 field sales representatives promoting VOWST are divided into two teams, comprised of 150 gastroenterology representatives and 20 hospital/infectious disease representatives. In addition, the production of VOWST commercial supply enabled a strong commercial launch within weeks of FDA approval and we continue to make progress expanding commercial-scale production of VOWST to prepare for anticipated future market demand.
- ***Completing the SER-155 Phase 1b study and 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 in an effort to reduce incidences of gastrointestinal infections, resulting bloodstream infections and GvHD. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT. Enrollment in the placebo-controlled cohort 2 portion of the study is ongoing, and the cohort 2 data readout is anticipated in the third quarter of 2024.
- ***Advance research and development activities supported by partnerships.*** Data from our SER-287 Phase 2b study and the first cohort of subjects from our SER-301 Phase 1b study in patients with mild-to-moderate UC suggest that the pharmacodynamic effects observed for SER-287 and SER-301 were greater in a subset of patients with IBD. Based on these results, we continue to advance research and development activities supported by partnerships to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts in IBD. In October 2023, we were awarded a $500,000 grant from the Crohn's & Colitis Foundation to leverage our clinical results and biological mechanism insights to functionally characterize subpopulations and to define associated biomarkers for IBD patient selection and stratification of patients where the gastrointestinal microbiome plays an active role in

inflammation and could be modified to reduce colitis. Our preclinical studies conducted to date, have recapitulated the patient subpopulation observations from the previously run trials and progressed associated biomarker delineation.

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 and knowledge base 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 healthy subjects and subjects with disease, or being treated for a disease, to delineate at high-resolution the profile of the microbiome (composition and function) and the physiological state of subjects 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, genes, or peptides 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, or 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 VOWST (developed as SER-109), SER-301, and SER-155 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. We have 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 with the desired profile and that is 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 VOWST and other potential commercial products. We addressed quality control requirements for VOWST using proprietary microbiological assays to assess the identity, potency, and purity of the final product.

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 product and product candidates represent a novel approach with potential application across a broad range of human diseases. Our first drug, VOWST, was approved by the FDA on April 26, 2023, to prevent recurrence of CDI in patients 18 or older following antibacterial treatment for recurrent CDI. VOWST is the first orally administered microbiome therapeutic approved by the FDA. We launched VOWST in the United States with our collaborator, Nestlé, in June 2023. Building upon VOWST, we are developing novel microbiome therapeutics, such as SER-155, to specifically target infections and antimicrobial resistance. We are evaluating SER-155 in a Phase 1b study in allo-HSCT recipients in an effort to reduce incidences of gastrointestinal infections, resulting bloodstream infections and GvHD. SER-155, an oral microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to prevent enteric-derived infections and resulting blood stream infections, as well as induce immune tolerance responses to reduce the incidence of GvHD in patients undergoing allo-HSCT. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT. Enrollment in the placebo-controlled cohort 2 portion of the study is ongoing, and the cohort 2 data readout is anticipated in the third quarter of 2024.

We have progressed additional preclinical stage programs to evaluate whether microbiome therapeutics may reduce the incidence of infection in indications such as chronic liver disease, cancer neutropenia, solid organ transplant, and AMR infections more broadly in high-risk settings such as intensive care units. Additional efforts in the early-stage portfolio are focused on the SER-301 program in IBD and programmatic objectives that are supported through a partnership with CCF. These efforts aim to leverage our clinical results and biological mechanism insights to functionally characterize patient subpopulations and to define associated biomarkers for IBD patient selection and stratification of patients where the gastrointestinal microbiome plays an active role in inflammation and could be modified to reduce colitis. 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 prioritize future drug targets and opportunities for combination therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

CDI Overview and VOWST

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, we estimated that there would 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. While fidaxomicin is indicated for the treatment of *C. difficile*-associated diarrhea, it does not have a label claim to reduce or prevent CDI recurrence. No antibiotic therapeutics are currently approved for the prevention of recurrent CDI.

Prevention of 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 can 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 CDI 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.

VOWST

VOWST (developed as SER-109) was approved by the FDA on April 26, 2023, to prevent recurrence of CDI in individuals 18 years of age or older following antibacterial treatment for recurrent CDI. VOWST is the first FDA-approved orally administered microbiome therapeutic, and consists of a consortium of purified Firmicutes spores designed to prevent recurrent CDI in patients with a history of CDI by modulating the microbiome to a state that resists *C. difficile* germination and growth. The VOWST manufacturing purification process is designed to remove unwanted microbes in an effort to reduce the risk of pathogen transmission beyond donor screening alone. We estimated that there were approximately 156,000 recurrent CDI 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 disease);
- 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 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), and thereby consistent with the results seen at eight weeks. 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.

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. We 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).

ECOSPOR IV was an open-label single-arm study evaluating SER-109 in 263 adult subjects with recurrent CDI. The safety results observed in ECOSPOR IV through 24 weeks showed that SER-109 was well tolerated, consistent with the safety profile observed in the prior completed Phase 3 study, ECOSPOR III. The ECOSPOR IV study results contributed to the SER-109 safety database and supported product approval. These data were published in the *JAMA Network Open* in February 2023.

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 VOWST in the United States and Canada. Under the terms of

the agreement, Nestlé assumed the role of lead commercialization party. We received an upfront license payment of $175 million in July 2021 and an additional $125 million in May 2023 following FDA approval of VOWST. The agreement also includes sales target milestones which, if achieved, could total up to $225 million. We were responsible for development and pre-commercialization costs in the United States. Following first commercial sale of VOWST, which occurred on June 2, 2023, we are entitled to share equally in its commercial profits and losses.

During the year ended December 31, 2023, Nestlé reported 1,284 VOWST units sold and $19.6 million in net sales, reflecting an estimated gross-to-net reduction of 13%, primarily due to returns reserve, prompt payment discounts, statutory discounts and rebates, and commercial rebates. The total collaboration loss for the year ended December 31, 2023 was $37.7 million. We record our 50% share of the collaboration loss, which includes commercial and medical affairs expenses incurred by us, on a net basis. Accordingly for the year ended December 31, 2023, our share of the VOWST net loss was $18.9 million.

As part of the commercialization of VOWST, we are closely monitoring the launch and focusing on a number of quantitative metrics. VOWST became commercially available in early June 2023. Broad demand for VOWST has been observed across both recurrent patients and healthcare providers since June 2023 (metrics noted below are based on data provided by Nestlé through December 31, 2023):

- Fourth quarter completed prescription enrollment forms received for VOWST were 1,322; of those 1,082 resulted in new patient starts by year-end 2023;
- From launch through year-end 2023, there were 2,833 completed prescription enrollment forms received for VOWST; of those 2,015 resulted in new patient starts by year-end 2023;
- In 2023, prescription enrollment forms were submitted by approximately 1,330 unique healthcare providers, or HCPs, since launch, with approximately 65% from gastroenterology and the remainder from other specialties; approximately 340 HCPs have prescribed VOWST to more than one patient; and
- VOWST demand has been observed across the recurrent CDI patient pool, including first recurrence, which is the largest recurrent CDI patient segment.

In close collaboration with Nestlé, we have scaled our HCP education efforts, worked to create a positive customer experience with faster and higher conversion of enrollments to new patient starts, and continued to establish payer coverage. Since the FDA approval of VOWST, Nestlé commercial customer facing field teams have been promoting VOWST and generating healthcare provider demand, including significant presence at both IDWeek and the American College of Gastroenterology, or ACG, meetings in October 2023. IDWeek and ACG are two of the largest infectious disease and gastroenterology conferences. Nestlé's 170 field sales representatives promoting VOWST are divided into two teams, comprised of 150 gastroenterology representatives and 20 hospital/infectious disease representatives.

The VOWST Voyage Support Program, or VOWST Voyage, was launched upon VOWST FDA approval to provide treatment and financial support for eligible patients. The VOWST Voyage staff work with healthcare providers and patients to convert patient enrollments into new patient starts and provide a robust high-touch customer experience.

Nestlé's payer field team continues to engage payers to build coverage, which would enable eligible patients to have access to VOWST as quickly and efficiently as possible. The team has been reinforcing what we believe to be a compelling value proposition for VOWST and is actively engaged with the three largest pharmacy benefit managers. In 2023, payers issued policies for VOWST coverage across plans representing 80% commercial and 54% Medicare Part D covered lives. Approximately 56% of the 1,082 fourth quarter new patient starts are being reimbursed through the patient's drug benefit.

We are investing in patient financial assistance to increase access to VOWST for patients with affordability challenges due to co-pays or other cost sharing requirements imposed on them by their insurer after the prescription has been approved. We believe that providing this type of patient access early on will contribute to a positive patient and provider experience, thus increasing demand over time. In terms of free drug utilization, we saw approximately 46% of 2023 new patient starts dispensed via our free drug programs, mostly for Medicare patients. We expect utilization of these programs to drop when the benefit design changes contained in the Inflation Reduction Act, which address patient cost sharing requirements in Medicare Part D plans, go into effect in 2025.

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, with the potential to reduce the rate of infections in medically compromised patients. Data from the SER-109 ECOSPOR III and ECOSPOR IV Phase 3 trial published in the *New England Journal of Medicine* (Feuerstadt et al., 2022) and *Journal of the American Medical Association* (Sims et al., 2023) suggest that microbiome therapeutics have the potential to restructure the gut microbiome and shift the gut metabolic landscape. Additional data show that SER-109 rapidly reduced the abundance of bacteria associated with common antibiotic resistance genes, or ARGs, and reduced ARG abundance in the gut (Straub et al., 2023). Collectively, we believe these data suggest the potential for microbiome therapeutics to restore colonization resistance and ultimately to reduce infections and antimicrobial resistance. We believe this Infection Protection approach may be replicable in

protecting a range of medically compromised patients from infections seeded by the gut microbiome and resulting downstream clinical sequelae. We believe this approach 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 in an effort to reduce incidences of gastrointestinal infections, resulting bloodstream infections and GvHD. SER-155, an oral microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to prevent enteric-derived infections and resulting blood stream infections, as well as induce immune tolerance responses to reduce the incidence of GvHD in patients undergoing allo-HSCT. SER-155 was designed using our reverse translational microbiome therapeutics development platform and 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 and pathogen domination in the gastrointestinal tract were significantly more likely to die due to infection and/or lethal GvHD (Peled et al., 2020). In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT.

The SER-155 Phase 1b study is designed to include approximately 70 patients in both an open-label (cohort 1) and a randomized, double-blind, placebo-controlled cohort (cohort 2) that will evaluate safety and tolerability before and after HSCT. Additionally, the engraftment of SER-155 bacteria (a measure of pharmacokinetics) and gastrointestinal pathogen domination, as well as the rates of enteric-derived infections and resulting blood stream infections, and GvHD will be evaluated.

Cohort 1 included 13 subjects who received any dosing of the SER-155 regimen, with 11 of these subjects subsequently receiving an allo-HSCT. Nine subjects had evaluable samples for microbiome data analysis. Gastrointestinal microbiome data from the first 100 days of cohort 1 showed the successful engraftment of SER-155 bacterial strains, and a substantial reduction in the cumulative incidence of pathogen domination as compared to a reference cohort of patients, a biomarker associated with the risk of serious enteric infections and resulting bloodstream infections as well as GvHD. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. We believe these initial SER-155 Phase 1b study results provide encouraging evidence to support further development of SER-155 to potentially reduce enteric-derived infections, resulting bloodstream infections, and GvHD in individuals undergoing allo-HSCT for cancers and other serious conditions. Study data from cohort 1 suggest that SER-155 administration results in significantly lower incidence rates of gastrointestinal dominations with pathogens of clinical concern, such as *Enterococcaceae, Enterobacteriaceae, Streptococcaceae*, and *Staphylococcaceae*.

Enrollment of cohort 2 is ongoing, incorporating a randomized, double-blinded placebo-controlled design to further evaluate safety, engraftment, and incidence of gastrointestinal ESKAPE microbiome pathogen domination, as well as the incidence of enteric infections, enteric driven blood stream infections, and GvHD. Cohort 2 subjects are administered either SER-155 or placebo at a 1:1 ratio. The study is being conducted at a number of leading cancer centers across the U.S. The cohort 2 data readout is anticipated in the third quarter of 2024.

Irritable Bowel Disease and Ulcerative Colitis

UC, a form of 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 is estimated to be 378 per 100,000, or approximately 1.25 million Americans (Lewis et al., 2023). 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 (Dlalal & Allegretti, 2022).

Currently, patients with UC require life-long therapy. Current medical therapies for the treatment of UC suppress the immune system rather than target reducing the triggers of immune activation and promoting immune tolerance. 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, are intolerant to the aminosalicylate class of medication, or where there are safety concerns relating to the use of immunomodulator or steroid therapy.

Current therapeutic approaches in IBD do not address the potential role of microbiome disruption in causing or aggravating disease in IBD. However, not all patients with IBD present with microbiome disruption; many patients with IBD demonstrate comparable taxonomic and functional microbiome diversity to healthy subjects (Lloyd-Price 2019). Similarly, pre-clinical models have shown that microbiomes from patients with IBD drive variable immune responses, with only a subset of microbiomes resulting in inflammation (Hart et al. 2017; Britton et al. 2019). These data suggest that the microbiome may play a role in a subset of subjects with IBD.

Data from our SER-287 Phase 2b study and the first cohort of subjects from our SER-301 Phase 1b study in patients with mild-to-moderate UC suggest that the pharmacodynamic effects observed for SER-287 and SER-301 were greater in a subset of patients with IBD. Based on these results, we continue to advance research and development activities supported by partnerships to evaluate

the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts in IBD. In October 2023, we were awarded a $500,000 grant from the Crohn's & Colitis Foundation, or CCF, to leverage our clinical results and biological mechanism insights to functionally characterize subpopulations and to define associated biomarkers for IBD patient selection and stratification of patients where the gastrointestinal microbiome plays an active role in inflammation and could be modified to reduce colitis. Our preclinical studies conducted to date, have recapitulated the patient subpopulation observations from the previously run trials and progressed associated biomarker delineation.

Manufacturing

Donor-derived product candidates

VOWST 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.

We operate two in-house stool donation centers in Irvine, California and Tempe, Arizona. 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. We have also established an internal Clinical Laboratory Improvement Amendments, or CLIA, and College of American Pathologists, or CAP, certified medical laboratory to support this screening, including high-throughput automated testing systems. 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 VOWST 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 and potency, and subsequently formulated into drug product where it is 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. We have validated the commercial manufacturing process and successfully completed pre-approval inspections conducted by the FDA. We believe we will be able to produce sufficient commercial supply of VOWST 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 VOWST 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, which is substantially complete, and is intended to provide manufacturing services for VOWST. Following final completion of the facility, we will initiate technology transfer and certain process qualification and validation activities prior to commencement of commercial manufacturing.

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 one of our Cambridge, Massachusetts locations 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 VOWST) 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) VOWST 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.

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 substantially complete; and (ii) provide manufacturing services to us for our VOWST 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 2023, the term of the Supply Agreement was extended through June 30, 2024.

Indebtedness

Loan and Security Agreement with Hercules

In October 2019, we entered into a loan and security agreement, or the Hercules Loan Agreement, with Hercules Capital, Inc., or Hercules, pursuant to which a term loan facility 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 Hercules 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. In February 2022, we entered into a Second Amendment to the Original Credit Facility (as amended by the First Amendment), or the Hercules Credit Facility, pursuant to which a term loan facility in the amount of $100.0 million became available to us in five tranches including the first tranche of $25.0 million previously drawn under the Original Credit Facility, subject to certain terms and conditions. The Hercules Credit Facility was repaid on the Oaktree Closing Date (as defined below).

Oaktree Credit Agreement

On April 27, 2023, or the Oaktree Closing Date, we entered into the Oaktree Credit Agreement, among the Company, the subsidiary guarantors from time to time party thereto, the Oaktree Lenders, and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Oaktree Lenders (in such capacity, the "Agent"). The Oaktree Credit Agreement establishes a term loan facility of $250.0 million, consisting of (i) $110.0 million, or the Tranche A Loan, funded on the Oaktree Closing Date, (ii) $45.0 million, or the Tranche B Loan, that the Company may borrow subject to certain conditions, (iii) $45.0 million, or the Tranche C Loan, that the Company may borrow subject to certain conditions, and (iv) $50.0 million, or the Tranche D Loan, available in Oaktree's sole discretion. The Tranche B Loan may be drawn by the Company until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least $35 million and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. The Tranche C Loan may be drawn until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $120 million and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Oaktree Term Loan has a maturity date of April 27, 2029, or the Oaktree Maturity Date. Of the $110.0 million Tranche A Loan advanced by the Lenders at closing, approximately $53.4 million repaid our existing credit facility with Hercules. After deducting other transaction expenses and fees, we received net proceeds of approximately $50.4 million.

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 VOWST and 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 VOWST and 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 potential inspection 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.

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, certain of 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 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 allows the trial to proceed, 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 among other things, 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 labeling.

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.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original BLAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the candidate is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

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 typically 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 any 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 indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or

manufacturing. If a CRL is issued, the sponsor must resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

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. 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. 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. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, depending on the design of the applicable clinical trials, 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, and the FDA may require that such studies be underway before granting any accelerated approval. 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 existing periods of regulatory exclusivity protection or patent terms, 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 disease or condition, 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 for the applicable disease or condition. Competitors, however, may receive approval of different therapeutic agents for the disease or condition for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different disease or condition than that for which the orphan product has exclusivity. Further, if a designated orphan product receives marketing approval for a disease or condition 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 (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). 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 Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, 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 EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, 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 for multi-center trials. 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 EU 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 EU 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 MA 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 or biological 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, protocol assistance, access to the centralized procedure, 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 or where the prevalence of the condition has increased above the threshold. 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, or QPPV, who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. 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, new legislation such as the CTR or in relation to orphan medicines is not applicable in Great Britain. The UK government has passed the 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. A new international recognition framework has been in place from January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new GB MA.

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.

In addition, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties for each wrongful act. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and civil False Claims Act, which can impose additional penalties associated with the wrongful act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of the Department of Health and Human Services emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud.

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 VOWST or 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 eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

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. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the drug price negotiation program is currently subject to legal challenges. 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 foreign 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

In November 2023, we announced the Restructuring Plan, which included a reduction in workforce of approximately 160 employees, or approximately 41% of our workforce. As of January 1, 2024, after the substantial implementation of the reduction in workforce in 2023, we had 233 full-time permanent employees. Thirty-nine employees work in administration, operations, and commercial and 194 work in research and development. None of our employees in the U.S. are currently represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

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 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 fostering high performing teams from all backgrounds; to ensuring that we attract, develop and retain diverse talent from all backgrounds; to increasing awareness within our company of unconscious biases, and supporting all employees, including those who may be 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 101 Cambridgepark Drive, Cambridge, Massachusetts 02140 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 commercial-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 $113.7 million for the year ended December 31, 2023, and $250.2 million for the year ended December 31, 2022. As of December 31, 2023, we had an accumulated deficit of $978.2 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 microbiome therapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have only had one product, VOWST, which was approved for marketing in the United States to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI on April 26, 2023, and launched in June 2023. We have not completed development of any of our other 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. While we plan to focus our investment on supporting commercialization of VOWST and on our SER-155 Phase 1b study in the near-term, our expenses may increase substantially in connection with our ongoing and future activities, particularly if and as we:

- commercialize and manufacture VOWST for adult patients with recurrent CDI with our collaborator Nestlé;
- continue the clinical development of SER-155 to potentially reduce incidences of gastrointestinal infections, resulting bloodstream infections, and GvHD in patients receiving allo-HSCT;
- advance research and development activities supported by partnerships;
- make strategic investments in manufacturing capabilities;
- maintain and augment our extensive proprietary microbiome therapeutic drug development know-how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire;
- establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we have obtained and in the future 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 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 have already obtained and may in the future 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 and commercialization 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 will require additional funding prior to the end of 2024. Because 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, 2023 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 VOWST and our product candidates, 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 if and as we scale up manufacturing operations and continue the commercialization of VOWST, continue the SER-155 Phase 1b study, and research, develop and initiate clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including 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 current or 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 impact of a continued increase in inflation rates or interest rates;
- the progress and results of our clinical studies;
- the cost of manufacturing VOWST and our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- our share of the profits and losses from commercial sales of VOWST pursuant to the 2021 License Agreement;
- the revenue, if any, received from commercial sales of any 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;
- the success of our Restructuring Plan announced in November 2023, which has been substantially implemented; 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 products or 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, the conflicts involving Ukraine and Russia and Israel and its surrounding regions, 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 VOWST or 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. Other than with respect to VOWST, which was approved by the FDA in April 2023, we have not yet demonstrated our ability to obtain regulatory approvals. Moreover, with the recent approval of VOWST, we have limited experience in demonstrating our ability to 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, including for example, the impact of our Restructuring Plan announced in November 2023 and substantially implemented by December 31, 2023, 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 VOWST, we are early in our development efforts of our product candidates 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 additional marketable drugs.

We are using our reverse translational microbiome therapeutics platform to develop microbiome therapeutic candidates. Other than VOWST, which launched in the United States in June 2023, we are at an early stage of development of our product candidates and our platform has not yet, and may never, lead to other approvable or marketable drugs. We are developing additional product candidates that we intend to develop 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, if approved, achieve market acceptance.

The success of our product and 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 and our product candidates, 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 our products or product candidates we will not be able to obtain product revenue or collaboration profit in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

VOWST and our product candidates are based on microbiome therapeutics, which is a novel approach to therapeutic intervention.

VOWST and our product candidates are based on microbiome therapeutics, 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. To our knowledge, VOWST is the first oral product based on this approach to receive FDA approval. We cannot be certain that our approach will lead to the development of additional approvable or marketable products or that we will be able to manufacture at commercial scale. Finally, the FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of novel product candidates 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 VOWST or 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.

Other than VOWST, which received FDA approval in April 2023 to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, 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 product candidates. Prior to approving a new therapeutic product, the FDA (or other regulatory authorities) generally requires that safety and efficacy, or with respect to biological products such as our microbiome therapeutic candidates, safety, purity and potency, 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.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators, IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the commercialization of our product candidates or otherwise adversely affect our business.

In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. 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 EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, 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 for multi-center trials. 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 EU 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 EU 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.

It is currently unclear to what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). 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 with the aim 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 UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will be closely watched and will determine how closely the UK regulations are aligned with the CTR. 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. On February 27, 2023, the UK Government and the European Commission reached a political agreement on the "Windsor Agreement" which will revise the Protocol on Ireland/Northern Ireland in order to address some of the perceived shortcomings in its operation. Once implemented, this may have further impact on the application of the CTR in Northern Ireland. A decision by the UK Government not to closely align any new legislation 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;
- 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. Other than FDA approval for VOWST in the United States to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, 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, or with respect to biologics such as our microbiome

therapeutic candidates, safety, purity and potency. 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. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council (not expected before early 2026) and may have a significant impact on the biopharmaceutical industry in the long term.

Additionally, regulatory authorities have substantial discretion in the approval process and may refuse to accept or file 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 are 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 submitting 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 have and may in the future 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. In December 2023, we received Fast Track designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT, and for SER-287 for the induction and maintenance of clinical remission in adults with mild-to-moderate UC. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Once granted, Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, and a BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections

of the BLA on a rolling basis before the complete application is submitted, 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 application.

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.

Prior to receiving FDA approval for VOWST, we received Breakthrough Therapy designation for SER-109 for treatment of CDI, and we may seek a Breakthrough Therapy designation for 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 also receive all of the Fast Track program features, including eligibility 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 a Breakthrough Therapy designation for 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 previously 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 and same disease or condition during 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 the EU. 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 designation, if the product is sufficiently profitable so that market exclusivity is no longer justified, or the prevalence of the condition has increased above the orphan designation threshold. 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. In connection with VOWST's approval, we received a seven year period of exclusivity to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, which period began on April 26, 2023.

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, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns continue to delay or 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 and/or VOWST could be adversely affected, 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 VOWST, 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 VOWST and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement, or the 2021 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 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 products and 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 or commercialization of any terminated products or discontinue any terminated products or product candidates, 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. For example, we must work closely with Nestlé to supply VOWST to them and coordinate scientific messaging. To optimize the commercial potential of VOWST, we must execute these plans effectively and collaboratively. 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 on Nestlé to provide information related to the commercialization of VOWST so that we can make strategic decisions and projections, and we may provide this data, or statements based upon this data, to investors. If the data Nestlé provides us is inaccurate or incomplete, it may adversely affect our financial statements, business operations, the commercial success of VOWST or our stock price.

Under the 2021 License Agreement, VOWST net sales are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. We rely on Nestlé to provide reporting related to net sales of VOWST in accordance with U.S. generally accepted accounting principles in order to calculate and record collaboration profit or loss. We also rely on Nestlé to provide timely, accurate and complete information related to the commercialization of VOWST, including data on prescribers, prescriptions and new patient starts. We use the information provided to us by Nestlé to report our results of operations, to plan for our future operations, and to make strategic decisions and projections, which may prove to be inaccurate or suboptimal. We base some of our strategic decisions and projections on the data Nestlé provides and we may provide this information to investors and analysts who may make their own predictions and estimates, all of which may prove to be inaccurate. Any failure by Nestlé to provide accurate and complete information related to the commercialization of VOWST, or to provide it on a timely basis, could adversely impact our financial statements, business operations, the commercial success of VOWST or our stock price.

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 data 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 and product candidates, 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 and 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 of VOWST and 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, VOWST and 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 VOWST and 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 VOWST or our product candidates have never produced any other FDA-approved therapeutic. One of the contract manufacturers on which we rely is constructing a building, which is substantially complete but remains under construction, to manufacture VOWST and our product candidates, however, upon completion, it may not be approved by the FDA for the manufacture of VOWST. 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.

Other than the manufacture of VOWST after its recent FDA approval, we have very little 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 and Waltham, Massachusetts locations where we conduct process development, scale-up activities and a portion of the manufacture of microbiome therapeutics as well as conduct quality control. 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. The FDA inspected our Cambridge and Waltham facilities in December 2022 and closed the inspections without issue. We currently intend to rely in part on third-party manufacturers for portions of the commercial manufacturing of VOWST and may establish a manufacturing facility for VOWST or any of our product candidates for production at a commercial scale. We have no experience in manufacturing, without reliance on third-party manufacturers, 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 Products, Product Candidates and Other Legal Matters

We depend heavily on the commercial success of VOWST, which was approved for marketing by the FDA in April 2023 and launched in the United States in June 2023. There is no assurance that our commercialization efforts, or those of our collaborators, in the United States with respect to VOWST will be successful or that we will be able to generate collaboration profit at the levels or within the timing we expect, or at the levels or within the timing necessary to support our goals for VOWST.

Our business currently depends heavily on our ability to successfully commercialize VOWST in the United States in its approved indication with our collaborator, Nestlé. We may never be able to successfully commercialize VOWST or meet our expectations with respect to collaboration profit. There is no guarantee that the infrastructure, systems, processes, policies, personnel, relationships and materials we have built in preparation for the launch and commercialization of VOWST in the United States will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not accept a new treatment paradigm for patients with recurrent CDI. We may also encounter challenges related to reimbursement of VOWST, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering VOWST. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. Our results may also be negatively impacted if we encounter deficiencies or inefficiencies in our infrastructure or processes. Any of these issues could impair our ability to successfully commercialize VOWST or to generate substantial collaboration profit or to meet our expectations with respect to the amount or timing of collaboration profit. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition and prospects. There is no guarantee that we will be successful in our commercialization efforts with respect to VOWST, or that we will generate significant collaboration profit from VOWST or any product candidate or become profitable.

Even though VOWST has received FDA approval and even if any of our product candidates receive marketing approval, VOWST and such product candidates 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.

Even though VOWST has received FDA approval to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, and even if any of our product candidates receive marketing approval, VOWST or our product candidates 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 alone, which are well established in the medical community or the use of FMT, and physicians may continue to rely on these treatments or the treatments of our competitors. If VOWST or our product candidates (if and when they are approved) do not achieve an adequate level of acceptance, we or our collaborators may not generate significant collaboration profit and we may not become profitable. The degree of market acceptance of VOWST or any of our product candidates, if approved, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which such 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 VOWST or any of 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 little experience in the sale, marketing, and distribution of pharmaceutical products. To achieve commercial success for VOWST or for any other product for which we obtain marketing approval, we will need to establish a sales and marketing organization and/or we will need our collaborator Nestlé to perform sales and marketing functions and they 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, including VOWST, in the United States and Canada. Under the 2021 License Agreement, Nestlé has the sole right to commercialize VOWST 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 VOWST in the 2021 Licensed Territory in

accordance with the commercialization plan. Both parties will perform medical affairs activities for VOWST in the 2021 Licensed Territory in accordance with a medical affairs plan. We were responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product, or VOWST, in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Since the first commercial sale of VOWST in June 2023, we are entitled to share equally in its commercial profits and losses.

In the future, we expect to build a focused sales and marketing infrastructure, or certain components of such infrastructure, if we were to market or co-promote VOWST and our product candidates, if and when they are approved in the United States and potentially elsewhere. 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 intend to rely and may increasingly rely on third parties, including Nestlé, to sell, market and distribute VOWST and our product candidates, if and when approved. 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 or collaboration profit 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 VOWST and our other 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 have or may in the future develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates 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 VOWST or any of our product candidates, if approved, 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 continue to commercialize VOWST or any of our 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 VOWST or 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 VOWST or any other 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 an even greater risk with the commercial sale of VOWST or any other 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;
- 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 develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $10.0 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, increase commercialization of VOWST, 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 VOWST or our product candidates.

Because we have received FDA approval of VOWST to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI, and if we obtain approval or any of our product candidates, 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 four 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, though the FDA may not approve an application relying on such data for a further eight years. 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.

VOWST qualified, and we believe that any of our product candidates approved as a biological product under a BLA should also qualify, for the 12-year period of reference product 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.

In the EU, 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 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 VOWST or 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.

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

VOWST and 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. For example, the FDA-approved label for VOWST includes certain warnings and precautions regarding transmissible infectious agents and the potential presence of food allergens.

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. For example, the FDA-approved label for VOWST includes a limitation of use that VOWST is not indicated for the treatment of CDI.

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.

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 we or our collaborators are found to have improperly promoted off-label uses of approved products, including VOWST or any of our product candidates that may be approved in the future, 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 VOWST and 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. The current FDA-approved indication for VOWST is limited to prevent the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for recurrent CDI. Physicians may nevertheless prescribe VOWST or a product candidate that is approved in future, if any, 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 VOWST or 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 VOWST and 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 VOWST and any other products for which we may in the future 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;

- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties;
- 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 products and 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 VOWST and our other 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 or commercializing;

- 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.

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, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, 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. Drug manufacturers' Medicaid Drug Rebate Program rebate liability was previously 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 price our products at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize VOWST or 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, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our ability to price our products appropriately, which could negatively impact 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 VOWST or 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 that impacts our ability to compete with other products or our ability to recoup our costs of developing our products, 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 various stages. We have successfully obtained multiple patents (both U.S. and foreign) in some patent families. In others, prosecution is at an early stage (e.g., provisional or PCT stage). For many 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 21 active patent application families (which includes exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 20 applications have been nationalized and one is at the PCT stage. While we have obtained 30 issued U.S. patents, 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, there can be no assurance that an alternative composition that may fall outside the scope of such claims will not be equally effective. Further, given that VOWST 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, 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 or product candidates. In addition, given the on-going prosecution of our portfolio, we continue development of our understanding of 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 any products or product candidates;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize VOWST or any of 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, 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 filed 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 VOWST and our product candidates, if approved, 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, VOWST or our product candidates, or use of VOWST or our product candidates 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 VOWST or 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, VOWST or our product candidates. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of VOWST or our product candidates, 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, VOWST or our product candidates or the use of VOWST or our product candidates. We are aware of several pending patent applications containing one or more claims that could be construed to cover VOWST, 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 VOWST, 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 VOWST, 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 VOWST, our product candidates 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 VOWST, 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 VOWST, our product candidates 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 VOWST or 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 VOWST or our product candidates. 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 VOWST or 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 VOWST or 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 VOWST or one of our product candidates, the defendant could counterclaim that the patent covering VOWST or 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 VOWST or 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 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 has been 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. 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

We may be unable to realize the expected benefits from our Restructuring Plan and our business might be adversely affected.

In November 2023, we announced that, based on a challenging macro environment and financial backdrop, a Restructuring Plan to focus our business operations to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while significantly reducing costs and supporting longer-term business sustainability. Under the Restructuring Plan, we reduced our workforce by approximately 41% and significantly scaled back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study. The Restructuring Plan has been substantially implemented.

These types of restructuring and cost reduction activities are complex and may result in unintended consequences and costs, such as unforeseen delays in the implementation of our strategic initiatives, business and operational disruptions, decreased employee morale and retention, loss of institutional knowledge and expertise, and potential impacts on financial reporting. The significant reduction in our workforce under the Restructuring Plan could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. In addition, the decision to significantly scale back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study may negatively impact our growth, competitive positioning, business and results of operations. If we do not successfully manage the impact of the Restructuring Plan or any other similar activities that we may undertake in the future, we may not achieve the expected costs savings and other expected benefits in the expected timeframe or at all, and our business, financial condition, and results of operations may be materially adversely affected.

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. Our Restructuring Plan may make it more difficult for us to hire qualified personnel. 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 and execution. 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.

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 with respect to VOWST and 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 VOWST, we rely on GenIbet in Portugal, and Bacthera, which has substantially completed 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, disruptions and instability in the banking industry and other parts of the financial services sector, 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;
- terrorism and/or political instability, unrest and wars, such as the conflicts involving Ukraine and Russia or Israel and its surrounding regions, 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 (including as a result of climate change), which could cause significant damage to the infrastructure upon which our business operations rely, and the timing, nature or severity of which we may be unable to prepare for;
- economic instability, 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 third-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 or unauthorized access, use, modification or disclosure, and the risk of our being unable to adequately monitor and audit and modify our controls over our confidential 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 continue to work 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. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, 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 technology systems or data, the costs associated with the investigation and remediation could be material. Any such real or perceived unauthorized access or use, breach, or other loss of confidential information could also result in regulatory scrutiny, reputational harm, legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, and regulatory enforcement, including penalties or fines. Notice of breaches may be required to affected individuals or state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such notifications could be costly, 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 that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and 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, as amended by the California Privacy Rights Act or collectively, CCPA, requires certain businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in other states, and continue to be proposed at the state and 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 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.

Furthermore, the Federal Trade Commission, or FTC, and many State Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the 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, or in the context of our activities within the 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 undertaking, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). 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, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the EU states that reliance on the standard contractual clauses, or SCCs - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-U.S. Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. 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 General Data Protection Regulation and Data Protection Act 2018, or collectively, the UK GDPR, 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 undertaking's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. 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 then 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, 2023, we had net operating loss carryforwards, or NOLs, of $527.1 million for federal income tax purposes and $504.2 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOLs subject to expiration begin to expire in various amounts in 2035. Our federal NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration, but may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020. Our state NOLs also begin to expire in various amounts in 2035. As of December 31, 2023, we also had federal and state research and development and other tax credit carryforwards of approximately $45.1 million and $7.7 million, respectively, net of uncertain tax position reserves, available to reduce future income tax liabilities, if any. 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 $25.9 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 rolling three-year period. Similar rules may apply under state tax laws. We have experienced ownership changes in the past, per a Section 382 study performed through December 31, 2020. We believe that none of our existing tax assets will expire unused as a result of the calculated limitations resulting from such ownership changes. However, we may have experienced additional ownership changes since December 31, 2020, and we may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we have undergone additional ownership changes, or if we undergo ownership changes in the future, 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.

The terms of the Oaktree Credit Agreement 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.

On April 27, 2023, we entered into the Oaktree Credit Agreement, which establishes a term loan facility of $250.0 million, consisting of (i) the Tranche A Loan, funded on the Oaktree Closing Date, (ii) the Tranche B Loan, that we may borrow subject to certain conditions, (iii) the Tranche C Loan, that we may borrow subject to certain conditions, and (iv) the Tranche D Loan, available in Oaktree's sole discretion (collectively with the Tranche A Loan, the Tranche B Loan, the Tranche C Loan, and the Tranche D Loan, the "Oaktree Term Loan"). We may draw the Tranche B Loan until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least $35.0 million and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. We may draw the Tranche C Loan until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $120.0 million and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Oaktree Term Loan has a maturity date of April 27, 2029 (the "Oaktree Maturity Date").

Our obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement) will be guaranteed by any of our domestic subsidiaries that become Guarantors (as defined in the Oaktree Credit Agreement), subject to certain exceptions. Our and our Guarantors' (collectively, the "Loan Parties") respective obligations under the Oaktree Credit Agreement and the other Loan Documents are secured by first priority security interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of December 31, 2023, there are no Guarantors.

The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including a financial covenant requiring us to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $30.0 million at all times commencing from 30 days after the Oaktree Closing Date and decreasing to $25.0 million of cash and cash equivalents in such controlled accounts after we borrow any Tranche B Loan. As of December 31, 2023, we were in compliance with all financial covenants pursuant to the Oaktree Credit Agreement.

In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause our indebtedness under the Oaktree Credit Agreement to become immediately due and payable, and to exercise remedies against the Loan Parties and the collateral securing the Oaktree Term Loan, including cash. Under the Oaktree Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Oaktree Credit Agreement (subject to specified cure periods with respect to certain payments), we or our subsidiaries breach any of the covenants under the Oaktree Credit Agreement (subject to specified cure periods with respect to certain breaches), a material adverse change occurs, we, our subsidiaries or our or their respective assets become subject to certain legal proceedings, such as bankruptcy proceedings, we and/or our subsidiaries are unable to pay our or their debts as they become due or default on contracts with third parties which would permit the holder of indebtedness in excess of a certain threshold to accelerate the maturity of such indebtedness or that could cause a material adverse change. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Oaktree Credit Agreement.

Any declaration by the Oaktree Lenders 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 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 43% of our outstanding voting stock as of December 31, 2023. As a result, if these stockholders were to choose to act together, they would be able to 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 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.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" as defined under the rules promulgated under the Exchange Act. We will remain a smaller reporting company until the fiscal year following the determination that both (i) the value of our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter and (ii) our annual revenues are more than $100 million during the most recently completed fiscal year and the value of our voting and non-voting common shares held by non-affiliates is $700 million or more as measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, or supplemental financial information.

We have elected to take advantage of certain of the reduced reporting obligations, and may in the future take advantage of these or others. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

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, the Oaktree Credit Agreement currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be 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:

- our ability to execute and realize the benefits of strategic plans, such as the Restructuring Plan we announced in November 2023;
- 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;
- the success of our commercialization efforts;

- 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. However, while we remain a non-accelerated filer, we will not be 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 laws, regulations, trends and stakeholder 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 or otherwise adversely impact our business.

Certain institutional investors, investor advocacy groups, investment funds, creditors and other influential financial market participants, as well as governments, regulators, customers, patients, employees and other stakeholders or third parties, have become increasingly focused on companies' ESG practices, including the impact of business on the environment and diversity, equity and inclusion matters. 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 may hinder the Company's access to capital.

Our reputation could be damaged if we do not, or are perceived not to, meet evolving stakeholder demand with respect to ESG matters, which could adversely affect our business, financial condition, profitability and cash flows. We may be criticized for our lack of ESG initiatives or goals or perceived as not taking sufficient action in connection with any of these matters. In turn, we may take certain actions, including the establishment of ESG-related goals or targets, to improve our ESG profile and/or respond to stakeholder demand; however, such actions may be costly or be subject to numerous conditions that are outside our control, and we cannot guarantee that we will meet these goals or targets or that such actions will have the desired effect even if met.

Additionally, we and/or other parties in our value chain are subject to, or are expected to be subject to additional climate and other ESG-related obligations arising from legislation and regulation in the United States, the European Union and other jurisdictions, including new reporting requirements, even as the availability and quality of the information that may be required to comply with such laws and regulations remains limited. We expect for our compliance costs with these laws and regulations to increase in future, and any failure, or perceived failure, by us to adhere to such laws and regulations, or meet evolving and varied stakeholder expectations and standards, could harm our business, reputation, financial condition, and operating results.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a security incident response plan.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework, or NIST CSF. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a security incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors who have access to our critical systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, “Risk Factors— Risks Related to Our Operations—Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.”

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of cybersecurity and other information technology risks. The Audit Committee oversees management’s implementation of our cybersecurity risk management program.

The Audit Committee receives quarterly reports from our Chief Information Officer, or CIO, on our cybersecurity risks. In addition, our CIO updates the Audit Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential. The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity.

Our management team, including our CIO, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our CIO has over three decades of IT experience in life sciences organizations. Her cybersecurity work includes the development and implementation of cybersecurity policies, platforms, and robust end-user training curriculums. Our CIO and IT Information Security Group work together to monitor and report cybersecurity trends and threats to management. Additionally, we work with an external IT partner and external cybersecurity counsel to assess, identify, and manage risks from cybersecurity threats. The IT Information Security Group undertakes table-top business disruption, disaster recovery and related response strategies, and plans on a periodic basis, and aims to review, and if appropriate update, applicable policies and procedures annually.

Our management team and IT Information Security Group supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other

information obtained from public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties

Research and Offices

Our corporate headquarters is located in Cambridge, Massachusetts, where we lease approximately 82,714 square feet of office, research, development, warehouse and laboratory space under a lease that expires in March 2033.

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

None.

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.

Holders

As of March 1, 2024, 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. 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, 2023.

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, 2023.

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 our financial condition and results of operations in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, such as statements regarding our plans, objectives, expectations, intentions and projections, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

A discussion regarding our financial condition and results of operations for the years ended December 31, 2023 and 2022, including a year-to-year comparison between 2023 and 2022, is presented below. For a discussion regarding our financial condition and results of operations for the year ended December 31, 2021, including a year-to-year comparison between 2022 and 2021, 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, 2022, filed with the SEC on March 7, 2023.

Overview

We are a commercial-stage microbiome therapeutics company focused on the development and commercialization of 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. Our first drug, VOWST (fecal microbiota spores, live-brpk), formerly called SER-109, was approved by the U.S. Food and Drug Administration, or FDA, on April 26, 2023, to prevent recurrence of *Clostridioides difficile* infection, or CDI, in patients 18 or older following antibacterial treatment for recurrent CDI. Our drug discovery and development pipeline includes other pre-clinical and clinical-stage assets. VOWST and our microbiome therapeutic candidates are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. We maintain a differentiated microbiome therapeutics drug discovery and development platform that includes good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality.

Our highest priority is the commercialization of VOWST in the United States, the first orally administered microbiome therapeutic approved by the FDA. We launched VOWST in the United States with our collaborator, Nestlé Health Science, or Nestlé, in June 2023.

We are also designing microbiome therapeutics optimized to decolonize pathogens and to modulate host function to both reduce and prevent infections and induce immune tolerance. 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, including pathogens that harbor antimicrobial resistance, or AMR.

In addition, we are evaluating SER-155 in a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HSCT, to prevent enteric-derived infections and resulting blood stream infections, as well as induce immune tolerance responses to reduce the incidence of graft-versus-host disease, or GvHD. In May 2023, we announced the Phase 1b cohort 1 results. Gastrointestinal microbiome data from the first 100 days of SER-155 Phase 1b open-label study cohort 1 showed the successful engraftment of SER-155 bacterial strains, and a substantial reduction in the cumulative incidence of pathogen domination as compared to a reference cohort of patients, a biomarker associated with the risk of serious enteric infections and resulting bloodstream infections, as well as GvHD in this patient population. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT. Enrollment in the placebo-controlled cohort 2 portion of the study is ongoing, and the cohort 2 data readout is anticipated in the third quarter of 2024.

We have progressed additional preclinical stage programs to evaluate whether microbiome therapeutics may reduce the incidence of infection in indications such as chronic liver disease, cancer neutropenia, solid organ transplant, and AMR infections more broadly in high-risk settings such as intensive care units, or ICUs. Additional efforts in the early-stage portfolio are focused on the SER-301 program in irritable bowel disease, or IBD, and programmatic objectives that are supported through a partnership with the Crohn's and Colitis Foundation, or CCF. These efforts aim to (i) confirm the functional phenotype and inflammatory state of patient subpopulations observed in our prior ulcerative colitis, or UC clinical trials, and (ii) prioritize inflammatory targets and evaluate 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 prioritize future drug targets and to identify opportunities for combination therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform and knowledge base for the discovery and development of microbiome therapeutics, and maintain extensive proprietary know-how that may be used to support future research and development efforts. 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. This platform and knowledge base enables both identification of specific microbes and microbial metabolites/peptides that are associated with disease and the design of therapeutic consortia of bacteria optimized for specific pharmacological properties. In addition, we own a valuable intellectual property estate related to the development and manufacture of microbiome therapeutics.

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.

Other than VOWST, our product candidates are still in preclinical development or early-stage discovery. Our ability to generate collaboration profit or product revenue sufficient to achieve profitability will depend heavily on the commercial success of VOWST, as well as 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 $113.7 million for the year ended December 31, 2023 and as of December 31, 2023, we had an accumulated deficit of $978.2 million.

In November 2023, we announced a restructuring plan, or the Restructuring Plan, to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while reducing costs and supporting longer-term business sustainability. The Restructuring Plan included (i) a reduction of our workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space. The Restructuring Plan was substantially implemented around the end of fiscal 2023. In connection with the Restructuring Plan, for the year ended December 31, 2023, we incurred approximately $5.6 million in restructuring costs, primarily related to the workforce reduction, of which $5.3 million are expected to result in cash expenditures, and the remaining $0.3 million relates to stock-based compensation expense associated with the acceleration of unvested equity awards. These costs were incurred in the fourth quarter of 2023. See Note 13, *Restructuring*, to our audited consolidated financial statements included elsewhere in this Annual Report.

We expect to achieve annual cash savings of approximately $75.0 million to $85.0 million in 2024, of which approximately $35.0 million is expected to result from the reduction in workforce, and which excludes any one-time charges primarily associated with the workforce reduction.

The foregoing estimates are based upon current assumptions and expectations but are subject to known and unknown risks and uncertainties. Accordingly, we may not be able to fully realize the cost savings and benefits initially anticipated from the Restructuring Plan, and the expected costs may over time be greater than initially expected. See "Risk Factors—Risks Related to Our Operations—*We may be unable to realize the expected benefits from our Restructuring Plan and our business might be adversely affected.*"

While we plan to focus our investment on supporting commercialization of VOWST and on our SER-155 Phase 1b study in the near-term, our expenses may increase in connection with future activities. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—*We are a commercial-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.*"

In addition, if we obtain marketing approval for any more of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including 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 pandemics, such as COVID-19, and increases in inflation rates or 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, 2023, we had cash and cash equivalents totaling $128.0 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 prior to the end of 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 issuances cannot be considered probable, as these events are outside our control. 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."

On February 22, 2024, our board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval at our annual meeting of stockholders to be held in 2024, by increasing the number of authorized shares of our Common Stock from 240,000,000 shares to 360,000,000 shares, or the Share Increase Amendment.

VOWST

VOWST was approved by the FDA on April 26, 2023, to prevent recurrence of CDI in individuals 18 years of age or older following antibacterial treatment for recurrent CDI. VOWST is the first FDA-approved orally administered microbiome therapeutic, and consists of a consortium of purified Firmicutes spores designed to prevent recurrent CDI in patients with a history of CDI by modulating the microbiome to a state that resists *C. difficile* germination and growth. The VOWST manufacturing purification process is designed to remove unwanted microbes in an effort to reduce the risk of pathogen transmission beyond donor screening alone. We estimate that there will be approximately 156,000 recurrent CDI cases in the United States during 2023.

We launched VOWST in the United States with our collaborator, Nestlé, in June 2023. Under the terms of the 2021 License Agreement, Nestlé is assuming the role of lead commercialization party. We received an upfront license payment of $175 million in July 2021 and an additional $125 million in May 2023 following FDA approval of VOWST. The agreement also includes sales target milestones which, if achieved, could total up to $225 million. We were responsible for development and pre-commercialization costs in the United States. Following first commercial sale of VOWST, which occurred on June 2, 2023, we are entitled to share equally in its commercial profits and losses.

During the year ended December 31, 2023, Nestlé reported 1,284 VOWST units sold and $19.6 million in net sales, reflecting an estimated gross-to-net reduction of 13%, primarily due to returns reserve, prompt payment discounts, statutory discounts and rebates, and commercial rebates. The total collaboration loss for the year ended December 31, 2023 was $37.7 million. We record our 50% share of the collaboration loss, which includes commercial and medical affairs expenses incurred by us, on a net basis. Accordingly for the year ended December 31, 2023, our share of the VOWST net loss was $18.9 million.

As part of the commercialization of VOWST, we are closely monitoring the launch and focusing on a number of quantitative metrics. VOWST became commercially available in early June. Broad demand for VOWST has been observed across both recurrent patients and healthcare providers since June 2023 (metrics noted below are based on data provided by Nestlé through December 31, 2023):

- Fourth quarter completed prescription enrollment forms received for VOWST were 1,322; of those 1,082 resulted in new patient starts by year-end 2023;
- From launch through year-end 2023, there were 2,833 completed prescription enrollment forms received for VOWST; of those 2,015 resulted in new patient starts by year-end 2023;
- In 2023, prescription enrollment forms were submitted by approximately 1,330 unique healthcare providers, or HCPs, since launch, with approximately 65% from gastroenterology and the remainder from other specialties; approximately 340 HCPs have prescribed VOWST to more than one patient; and
- VOWST demand has been observed across the recurrent CDI patient pool, including first recurrence, which is the largest recurrent CDI patient segment.

In close collaboration with Nestlé, we have scaled our HCP education efforts, worked to create a positive customer experience with faster and higher conversion of enrollments to new patient starts, and continued to establish payer coverage. Since the FDA approval of VOWST, Nestlé commercial customer facing field teams have been promoting VOWST and generating healthcare provider demand, including significant presence at both IDWeek and the American College of Gastroenterology, or ACG, meetings in October 2023. IDWeek and ACG are two of the largest infectious disease and gastroenterology conferences. Nestlé's 170 field sales representatives promoting VOWST are divided into two teams, comprised of 150 gastroenterology representatives and 20 hospital/infectious disease representatives.

The VOWST Voyage Support Program, or VOWST Voyage, was launched upon VOWST FDA approval to provide treatment and financial support for eligible patients. The VOWST Voyage staff work with healthcare providers and patients to convert patient enrollments into new patient starts and provide a robust high-touch customer experience.

Nestlé's payer field team continues to engage payers to build coverage, which would enable eligible patients to have access to VOWST as quickly and efficiently as possible. The team has been reinforcing what we believe to be a compelling value proposition for VOWST and is actively engaged with the three largest pharmacy benefit managers. In 2023, payers issued policies for VOWST

coverage across plans representing 80% commercial and 54% Medicare Part D covered lives. Approximately 56% of the 1,082 fourth quarter new patient starts are being reimbursed through the patient's drug benefit.

We are investing in patient financial assistance to increase access to VOWST for patients with affordability challenges due to co-pays or other cost sharing requirements imposed on them by their insurer after the prescription has been approved. We believe that providing this type of patient access early on will contribute to a positive patient and provider experience, thus increasing demand over time. In terms of free drug utilization, we saw approximately 46% of 2023 new patient starts dispensed via our free drug programs, mostly for Medicare patients. We expect utilization of these programs to drop when the benefit design changes contained in the Inflation Reduction Act, which address patient cost sharing requirements in Medicare Part D plans, go into effect in 2025.

VOWST was previously granted Breakthrough Therapy and Orphan Drug Designations by the FDA. In connection with the FDA approval of VOWST, we received seven years of orphan-drug exclusivity, which began on April 26, 2023. During that time, VOWST 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 the same disease or condition during that time period, except under certain circumstances.

The FDA approval of VOWST was supported by the Phase 3 development program that included the ECOSPOR III and ECOSPOR IV studies. ECOSPOR III 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 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), and thereby consistent with the results seen at eight weeks. 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.

ECOSPOR IV was an open-label single-arm study evaluating SER-109 in 263 adult subjects with recurrent CDI. 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. The ECOSPOR IV study results contributed to the SER-109 safety database and supported product approval. These data were published in the *JAMA Network Open* in February 2023.

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 ECOSPOR III and ECOSPOR IV Phase 3 trial published in the *New England Journal of Medicine* (Feuerstadt et al., 2022) and *Journal of the American Medical Association* (Sims et al., 2023) suggest that microbiome therapeutics have the potential to restructure the gut microbiome and shift the gut metabolic landscape. Additional data show that SER-109 rapidly reduced the abundance of bacteria associated with common antibiotic resistance genes, or ARGs, and reduced ARG abundance in the gut (Straub et al., 2023). Collectively, we believe these data suggest the potential for microbiome therapeutics to restore colonization resistance and ultimately to reduce infections and antimicrobial resistance. We believe this Infection Protection approach may be replicable in protecting a range of medically compromised patients from infections seeded by the gut microbiome and resulting downstream clinical sequelae. We believe this approach 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 in an effort to reduce incidences of gastrointestinal infections, resulting bloodstream infections and GvHD. SER-155, an oral microbiome therapeutic candidate consisting of a consortium of cultivated bacteria, is designed to prevent enteric-derived infections and resulting blood stream infections, as well as induce immune tolerance responses to reduce the incidence of GvHD in patients undergoing allo-HSCT. SER-155 was designed using our reverse translational microbiome therapeutics development platform and 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 and pathogen domination in the gastrointestinal tract were significantly more likely to die due to infection and/or lethal GvHD (Peled et al., 2020). In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in allo-HSCT patients.

The SER-155 Phase 1b study is designed to include approximately 70 patients in both an open-label (cohort 1) and a randomized, double-blind, placebo-controlled cohort (cohort 2) that will evaluate safety and tolerability before and after HSCT.

Additionally, the engraftment of SER-155 bacteria (a measure of pharmacokinetics) and gastrointestinal pathogen domination, as well as the rates of enteric-derived infections and resulting blood stream infections, and GvHD will be evaluated.

Cohort 1 was designed to assess safety and drug pharmacology including the engraftment of drug bacteria in the gastrointestinal tract. Cohort 1 included 13 subjects who received any dosing of the SER-155 regimen, with 11 of these subjects subsequently receiving an allo-HSCT. Nine subjects had evaluable samples for microbiome data analysis. Gastrointestinal microbiome data from the first 100 days of cohort 1 showed the successful engraftment of SER-155 bacterial strains, and a substantial reduction in the cumulative incidence of pathogen domination as compared to a reference cohort of patients, a biomarker associated with the risk of serious enteric infections and resulting bloodstream infections as well as GvHD. The tolerability profile results were favorable, with no serious adverse events attributed to SER-155 administration. Stem cell engraftment was observed in all subjects. We believe these initial SER-155 Phase 1b study results provide encouraging evidence to support further development of SER-155 to potentially reduce enteric-derived infections, resulting bloodstream infections, and GvHD in individuals undergoing allo-HSCT for cancers and other serious conditions. We also believe the available study data from cohort 1 suggest that SER-155 administration results in significantly lower incidence rates of gastrointestinal dominations with pathogens of clinical concern, such as *Enterococcaceae, Enterobacteriaceae, Streptococcaceae, and Staphylococcaceae*.

Enrollment of cohort 2 is ongoing, incorporating a randomized, double-blinded placebo-controlled design to further evaluate safety, engraftment, and incidence of gastrointestinal ESKAPE microbiome pathogen domination, as well as the incidence of enteric infections, enteric driven blood stream infections, and GvHD. Cohort 2 subjects are administered either SER-155 or placebo at a 1:1 ratio. The study is being conducted at a number of leading cancer centers across the U.S. The cohort 2 data readout is anticipated in the third quarter of 2024.

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, pursuant to an exclusive license to certain intellectual property from Memorial Sloan Kettering Cancer Center, with a patent term running until at least 2035, we are responsible for paying a 2.5% royalty on net sales of VOWST, minimum annual royalties, and milestone payments. The milestone payments are based on VOWST target sales milestones, the first being $1.0 million which was payable upon the first commercial sale of VOWST and paid in July 2023, the second being $2.5 million payable upon annual VOWST sales of $100.0 million, and the last being $10.0 million payable upon annual VOWST sales of $500.0 million. 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 VOWST extend through 2034, through 2041 for SER-155, and through 2040 for SER-301. We plan on continuing to broaden our patent portfolio. Currently, we have 21 active patent application families, which includes 20 nationalized applications and one at the PCT stage. To date, we have obtained 30 issued U.S. patents.

Regulatory Exclusivity

If we obtain marketing approval for any of our product candidates, we expect to receive reference product exclusivity against biosimilar products. For example, VOWST (which was recently approved by the FDA) has a 12-year period of exclusivity in the United States. In the European Union, new molecular entities generally receive eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization.

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. Under our 2021 License Agreement with Nestlé, beginning with the first commercial sale of VOWST, which occurred in June 2023, net sales of VOWST are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. We record our share of the net profits or losses from the sales of VOWST, including our commercial and medical affairs expenses, on a net basis, pursuant to the terms of the 2021 License Agreement. See *Collaboration (Profit) Loss Sharing - related party* below, and also "–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 consolidated 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 anticipate an overall decrease in research and development expenses beginning in 2024, as we expect the Restructuring Plan to significantly reduce research and development activities other than the completion of the SER-155 Phase 1b study. Research and development expenses may increase in the future as we initiate technology transfer activities with Bacthera and prepare for qualification of the Bacthera manufacturing facility, and if and as we resume development of any clinical or preclinical programs.

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 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. Prior to the commercial launch of VOWST, general and administrative expenses also included professional service fees for marketing and market access activities to commercialize VOWST.

We expect that our general and administrative expenses will decrease starting in 2024 as the Restructuring Plan is expected to result in a reduction of personnel expenses due the workforce reduction and a reduction in external expenses including the elimination of non-essential expenses and consolidation of office space. General and administrative expenses may increase as we undertake efforts from time to time to raise additional capital. We may also 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

Under the 2021 License Agreement with Nestlé, VOWST net sales are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. We record our share of the profits or losses from the sales of VOWST, including our commercial and medical affairs expenses, on a net basis, as collaboration (profit) loss sharing - related party. This treatment is in accordance with our revenue recognition and collaboration policy, given that Nestlé and we are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the

activities in the arrangement. Nestlé provides us with reporting related to net sales of VOWST in accordance with U.S. generally accepted accounting principles in order to calculate and record collaboration profit or loss.

The collaboration (profit) loss sharing - related party line item also includes our profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over our cost to manufacture VOWST, subject to a supply price cap.

The collaboration (profit) loss sharing - related party line item also includes collaboration loss related to pre-launch activities, which were completed prior to the first commercial sale of VOWST in June 2023.

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 Capital, Inc. and Oaktree, including the accretion of the discount on our Oaktree Term Loan.

Other (Expense) Income

Other (expense) income primarily consists of amortization of premiums or accretion of discounts on investments, and changes in the fair values of our warrant liabilities associated with our Oaktree Term Loan.

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, 2023, we had federal and state net operating loss carryforwards of $527.1 million and $504.2 million, respectively, both of which begin to expire in 2035. As of December 31, 2023, we also had federal and state research and development tax credit carryforwards of $45.1 million and $7.7 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 $25.9 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. 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.

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. We record our share of the profits or losses from the sales of VOWST on a net basis as collaboration (profit) loss sharing - related party because Nestlé and we are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the arrangement. The collaboration (profit) loss sharing - related party line item also includes our profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over our cost to manufacture VOWST.

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, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022.

	Year Ended December 31,		
	2023	2022	Change
		(in thousands)	
Revenue:			
Collaboration revenue - related party	$ 126,325	$ 7,128	$ 119,197
Total revenue	126,325	7,128	119,197
Operating expenses:			
Research and development	145,860	172,920	(27,060)
General and administrative	87,744	79,694	8,050
Collaboration (profit) loss sharing - related party	704	1,004	(300)
Total operating expenses	234,308	253,618	(19,310)
Loss from operations	(107,983)	(246,490)	138,507
Other (expense) income:			
Interest income	7,301	3,058	4,243
Interest expense	(13,176)	(6,020)	(7,156)
Other income (expense)	134	(705)	839
Total other expense, net	(5,741)	(3,667)	(2,074)
Net loss	$ (113,724)	$ (250,157)	$ 136,433

Revenue

Total revenue was $126.3 million and $7.1 million for the years ended December 31, 2023 and 2022, respectively. The increase in total revenue of $119.2 million was primarily due to the milestone payment of $125.0 million received from our collaborator Nestlé, upon FDA approval of VOWST. The increase was partially offset by a $3.7 million decrease in collaboration revenue

attributable to the services performed pursuant to the 2016 License Agreement and a $2.1 million decrease in collaboration revenue attributable to the services performed pursuant to the 2021 License Agreement.

Research and Development Expenses

	Year Ended December 31,		
	2023	2022	Change
	(in thousands)		
Microbiome therapeutics platform	$ 44,062	$ 37,857	$ 6,205
VOWST	17,871	48,649	(30,778)
SER-155	7,759	5,069	2,690
Early stage programs	1,245	1,759	(514)
Total direct research and development expenses	70,937	93,334	(22,397)
Personnel-related (including stock-based compensation)	74,923	79,586	(4,663)
Total research and development expenses	$ 145,860	$ 172,920	$ (27,060)

Research and development expenses were $145.9 million for the year ended December 31, 2023, compared to $172.9 million for the year ended December 31, 2022. The decrease of $27.1 million was due primarily to the following:

- a decrease in personnel-related costs of $4.7 million, primarily due to a decrease of $13.3 million resulting from the capitalization of certain labor costs into inventory beginning with the commercialization of VOWST, and a decrease of $2.0 million resulting from the receipt of payroll tax credits, partially offset by an increase of $2.5 million in salaries, bonus, and employee benefits expenses, a $5.9 million increase in stock-based compensation expense, which was primarily as a result of options and awards with performance conditions that were achieved during the year following the FDA approval of VOWST, and a $2.2 million increase in employee post-termination benefits due to the Restructuring Plan (see Note 13, *Restructuring*, to our audited consolidated financial statements included elsewhere in this Annual Report);
- a decrease of $30.8 million in expenses related to our VOWST program, primarily due to a decrease in clinical trial costs of $12.6 million, and a decrease of $12.0 million in lab supplies and consumables and facility-related costs, as we have capitalized certain of these costs into inventory in conjunction with the commercialization of VOWST. The total decrease is also attributable to a decrease of $6.0 million in consulting and professional fees and a decrease of $0.2 million in analytical testing and other manufacturing costs;
- a decrease of $0.5 million in expenses of our early stage programs, primarily driven by reduced clinical trial costs of $1.2 million, partially offset by an increase in analytical testing of $0.7 million;

partially offset by:

- an increase of $6.2 million in research expenses related to our microbiome therapeutics platforms, primarily due to an increase of $7.0 million in facilities costs, lab supplies, and consumables, driven primarily by our new and amended lease agreements for laboratory and office spaces in Massachusetts and Pennsylvania, and an increase of $1.6 million in consulting and professional fees, partially offset by a decrease of $2.2 million in analytical testing expenses, and a decrease of $0.2 million in clinical trial costs and other manufacturing costs;
- an increase of $2.7 million in expenses related to our SER-155 program due to an increase in clinical trial and other manufacturing costs.

General and Administrative Expenses

	Year Ended December 31,		
	2023	2022	Change
	(in thousands)		
Personnel-related (including stock-based compensation)	$ 36,629	$ 31,277	$ 5,352
Professional fees	28,446	32,260	(3,814)
Facility-related and other	22,669	16,157	6,512
Total general and administrative expenses	$ 87,744	$ 79,694	$ 8,050

General and administrative expenses were $87.7 million for the year ended December 31, 2023, compared to $79.7 million for the year ended December 31, 2022. The increase of $8.1 million was primarily due to the following:

- an increase in personnel-related costs of $5.4 million, due to an increase of $1.0 million in salaries, bonus, payroll taxes and employee benefit expenses, a $1.7 million increase in employee post-termination benefits due to the Restructuring Plan (see Note 13, *Restructuring*, to our audited consolidated financial statements included elsewhere in this Annual Report), and a $2.7 million increase in stock-based compensation expense, which was primarily the result of options and awards with performance conditions that were achieved during the year ended December 31, 2023 upon FDA approval of VOWST, partially offset by the reversal of stock-based compensation expense associated with the forfeiture of unvested awards; and
- an increase in facility-related and other costs of $6.5 million, due to increases in laboratory and office rent expenses of $3.8 million and an increase in information technology costs of $2.7 million; partially offset by
- a decrease in professional fees of $3.8 million, due to a $9.8 million decrease in professional services, consulting and recruiting fees, offset by a $6.0 million increase in legal expenses primarily due to certain transaction and milestone payments due to third parties as a result of the FDA approval of VOWST.

Collaboration (Profit) Loss Sharing - related party

Collaboration (profit) loss sharing – related party resulted in $0.7 million of expense for the year ended December 31, 2023, compared to $1.0 million of expense for the year ended December 31, 2022. Beginning with the commercial launch of VOWST in June 2023, we record our share of the net profits and losses from the sales of VOWST, which are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions, as collaboration (profit) loss sharing - related party. Our share of VOWST net profits and losses also includes commercial and medical affairs expenses incurred by us. For the year ended December 31, 2023, our share of the VOWST net loss was $18.9 million. We also record as collaboration (profit) loss sharing - related party our net profit on the transfer of VOWST to Nestlé, as well as our share of pre-launch expenses. For the year ended December 31, 2023, these amounts were $23.3 million in net profit and $5.1 million in net loss, respectively.

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. The $1.0 million of expense recorded for the year ended December 31, 2022 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 us.

The components of the collaboration (profit) loss sharing - related party are as follows (in thousands):

	For the Year Ended December 31,		
	2023	2022	2021
Share of VOWST net loss	$ 18,873	$ —	$ —
Profit on transfer of VOWST inventory to Nestlé	(23,327)	—	—
Collaboration (profit)/loss related to pre-launch activities	5,158	1,004	(1,732)
Total collaboration (profit) loss sharing - related party	$ 704	$ 1,004	$ (1,732)

Other (Expense) Income, Net

Other (expense) income, net was $5.7 million of expense for the year ended December 31, 2023 compared to $3.7 million of expense for the year ended December 31, 2022. The increase in other expense, net was primarily due to an increase in interest expense of $7.1 million as a result of higher interest rates and a higher borrowing base with the Oaktree Term Loan. This increase was partially offset by an increase in other income of $0.8 million and an increase in interest income of $4.3 million.

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.

On February 22, 2024, our board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval at our annual meeting of stockholders to be held in 2024, by increasing the number of authorized shares of our common stock from 240,000,000 shares to 360,000,000 shares, or the Share Increase Amendment. Our board of directors believes it is in the best interests of us and our stockholders to increase our authorized shares of common stock in order to have additional shares available for use as our board of directors deems appropriate or necessary. As such, the primary purpose of the Share Increase Amendment is to provide us with greater flexibility with respect to managing our common stock in connection with such corporate purposes as may, from time to time, be considered advisable by our Board. These corporate purposes could include, without limitation, financing activities, public or private offerings of common stock, stock dividends or splits, conversions of convertible securities, issuance of options and other equity awards pursuant to our incentive plans, establishing a strategic relationship with a corporate collaborator and acquisition transactions.

In May 2021, we entered into a Sales Agreement, or the 2021 Sales Agreement, with Cowen and Company, LLC, or 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 "at-the-market" equity offering program under which Cowen acts as sales agent. During the year ended December 31, 2023, we sold 7,711,199 shares of common stock under the 2021 Sales Agreement, at an average price of approximately $2.46 per share, raising aggregate net proceeds of approximately $18.2 million after deducting an aggregate commission of approximately 3% and other issuance costs. During the year ended December 31, 2022, we sold 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 $4.4 million after deducting an aggregate commission of approximately 3%. Between December 31, 2023 and February 29, 2024, we sold 15,366,630 shares of common stock under the 2021 Sales Agreement, at an average price of approximately $1.23 per share, raising aggregate net proceeds of approximately $18.5 million after deducting an aggregate commission of approximately 3% and other issuance costs.

As of December 31, 2023, we had cash and cash equivalents totaling $128.0 million and an accumulated deficit of $978.2 million. For the year ended December 31, 2023, we incurred a net loss of $113.7 million, and used cash in operations of $117.4 million. We expect that our operating losses and negative cash flows will continue for the foreseeable future.

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 ability to obtain sufficient additional equity or debt financing with terms favorable or acceptable to us cannot be considered probable, as these events are outside of our control. Based on our currently available cash resources, we will require additional funding prior to the end of 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.

Restructuring Plan

In November 2023, we announced the Restructuring Plan to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while reducing costs and supporting longer-term business sustainability. The Restructuring Plan included (i) a reduction of our workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space. The Restructuring Plan was substantially implemented around the end of fiscal 2023. In connection with the Restructuring Plan, for the year ended December 31, 2023, we incurred approximately $5.6 million in restructuring costs, primarily related to the workforce reduction, of which $5.3 million are expected to result in cash expenditures, and the remaining $0.3 million relates to stock-based compensation expense associated with the acceleration of unvested equity awards. These costs were incurred in the fourth quarter of 2023. See Note 13, *Restructuring*, to our audited consolidated financial statements included elsewhere in this Annual Report. We expect to achieve annual cash savings of approximately $75.0 million to $85.0 million in 2024, of which approximately $35.0 million is expected to result from the reduction in workforce, and which excludes any one-time charges primarily associated with the workforce reduction.

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 VOWST, 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 VOWST (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. 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.

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 VOWST and for Phase 3 clinical trials for VOWST. 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 VOWST 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 VOWST 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 VOWST) 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) VOWST 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 were responsible for, and used commercially reasonable efforts in, conducting development of VOWST in the 2021 Field in the United States until first regulatory approval for VOWST was 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 the 2021 Collaboration Products in the 2021 Field in the 2021 Licensed Territory, at our cost, except that expenses incurred for regulatory activities approved by a joint steering committee pursuant to a life cycle management plan for the 2021 Collaboration Products are shared equally between the parties. We are now solely responsible for manufacturing and supplying VOWST for development in the 2021 Field in the 2021 Licensed Territory.

Nestlé has the sole right to commercialize VOWST 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 VOWST in the 2021 Licensed Territory in accordance with the commercialization plan. Both parties will perform medical affairs activities for VOWST in the 2021 Licensed Territory in accordance with a medical affairs plan. We are solely responsible for the manufacturing and supply of VOWST for commercialization under a supply agreement that has been executed between the parties. We were responsible for commercialization and medical affairs activities costs incurred by the parties until first commercial sale of the first 2021 Collaboration Product, or VOWST, in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. Since the first commercial sale of VOWST in June 2023, we are 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 VOWST, which we received in May 2023, $10.0 million upon Canadian regulatory approval of VOWST, 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 VOWST 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 with twelve months' prior written notice, effective only on or after the third anniversary of first commercial sale of VOWST in the 2021 Licensed Territory. 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 substantially complete; and (ii) provide manufacturing services to us for VOWST 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 $301 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, or the Hercules Loan Agreement, with Hercules Capital, Inc., or Hercules, pursuant to which a term loan facility 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 Hercules 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, we entered into a Second Amendment to the Original Credit Facility (as amended by the First Amendment), or the Hercules Credit Facility, pursuant to which a term loan facility in the amount of $100.0 million became available to us in five tranches including the first tranche of $25.0 million previously drawn under the Original Credit Facility, subject to certain terms and conditions.

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

The Hercules Credit Facility was repaid on the Oaktree Closing Date (as defined below). For a further description of the Hercules Credit Facility, see Note 9 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Oaktree Credit Agreement

On April 27, 2023, or the Oaktree Closing Date, we entered into the Oaktree Credit Agreement, among the Company, the subsidiary guarantors from time to time party thereto, the Oaktree Lenders, and the Agent. The Oaktree Credit Agreement establishes a term loan facility of $250.0 million, consisting of (i) $110.0 million, or the Tranche A Loan, funded on the Closing Date, (ii) $45.0 million, or the Tranche B Loan, that the Company may borrow subject to certain conditions, (iii) $45.0 million, or the Tranche C Loan, that the Company may borrow subject to certain conditions, and (iv) $50.0 million, or the Tranche D Loan, available in Oaktree's sole discretion. The Tranche B Loan may be drawn by the Company until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least $35 million and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. The Tranche C Loan may be drawn until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $120 million and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Oaktree Term Loan has a maturity date of April 27, 2029, or the Oaktree Maturity Date. Of the $110.0 million Tranche A Loan advanced by the Lenders at closing, approximately $53.4 million repaid the Company's then-existing credit facility with Hercules Capital, Inc. After deducting other transaction expenses and fees, the Company received net proceeds of approximately $50.4 million.

Borrowings under the Oaktree Term Loan bear interest at a rate per annum equal to the three-month term Secured Overnight Financing Rate (subject to a 2.500% floor and a 5.000% cap), plus an applicable margin of 7.875%, payable quarterly in arrears. If certain VOWST net sales targets are met, the applicable margin will be reduced from 7.875% to 7.50% through the Oaktree Maturity Date. We are required to make quarterly interest-only payments on the Oaktree Term Loan for the first three years after the Oaktree Closing Date. Beginning on June 30, 2026, we will be required to make quarterly payments of interest, plus repay 7.5% of the outstanding principal of the Oaktree Term Loan in quarterly installments until the Oaktree Maturity Date, unless the interest only period is extended based upon the achievement of certain VOWST net sales targets.

We are obligated to pay the Oaktree Lenders an exit fee equal to 1.50% of the aggregate amount of the Oaktree Term Loan funded, such exit fee to be due and payable upon the earliest to occur of (1) the Oaktree Maturity Date, (2) the acceleration of the outstanding Oaktree Term Loan, and (3) the prepayment of the outstanding Oaktree Term Loan. We may voluntarily prepay the outstanding Oaktree Term Loan, subject to a customary make-whole for the first two years following the Oaktree Closing Date plus 4.0% of the principal amount of the Oaktree Term Loan prepaid, and thereafter a prepayment premium equal to (i) 4.0% of the principal amount of the Oaktree Term Loan prepaid, if prepaid after the second anniversary of the Oaktree Closing Date through and including the third anniversary of the Oaktree Closing Date, (ii) 2.0% of the principal amount of the Oaktree Term Loan if prepaid after the third anniversary of the Oaktree Closing Date through and including the fourth anniversary of the Oaktree Closing Date, (iii) 1.0% of the principal amount of the Oaktree Term Loan if prepaid after the fourth anniversary of the Oaktree Closing Date through

and including the fifth anniversary of the Oaktree Closing Date, with no prepayment premium due after the fifth anniversary of the Oaktree Closing Date through the Oaktree Maturity Date.

Our obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement) will be guaranteed by any of our domestic subsidiaries that become Guarantors (as defined in the Oaktree Credit Agreement), subject to certain exceptions. Our and our Guarantors', or collectively, the Loan Parties, respective obligations under the Oaktree Credit Agreement and the other Loan Documents are secured by first priority security interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of December 31, 2023, there were no Guarantors.

The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including a financial covenant requiring us to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $30.0 million at all times commencing from 30 days after the Oaktree Closing Date and decreasing to $25.0 million of cash and cash equivalents in such controlled accounts after we borrow any Tranche B Loan. As of December 31, 2023, we were in compliance with all financial covenants pursuant to the Oaktree Credit Agreement.

In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause our indebtedness under the Oaktree Credit Agreement to become immediately due and payable, and to exercise remedies against the Loan Parties and the collateral securing the Oaktree Term Loan, including cash. Under the Oaktree Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Oaktree Credit Agreement (subject to specified periods), we or our subsidiaries breach any of the covenants under the Oaktree Credit Agreement (subject to specified cure periods with respect to certain breaches), a material adverse change occurs, we, our subsidiaries or our or their respective assets become subject to certain legal proceedings, such as bankruptcy proceedings, we and/or our subsidiaries are unable to pay our or their debts as they become due or default on contracts with third parties which would permit the holder of indebtedness in excess of a certain threshold to accelerate the maturity of such indebtedness or that could cause a material adverse change. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Oaktree Credit Agreement.

On the Oaktree Closing Date, we issued to the Oaktree Lenders of such Tranche A Loan warrants to purchase 647,589 shares (subject to certain adjustments) of our common stock, or the Warrant, at an exercise price per share of $6.69. The Tranche A Warrant is immediately exercisable and the exercise period expires on April 26, 2030. Upon the funding of each of the Tranche B Loan and the Tranche C Loan, we are required to issue to the Oaktree Lenders of the Oaktree Term Loan warrants to purchase 264,922 shares (subject to certain adjustments) of the Company's common stock on each such funding date at an exercise price equal to the trailing volume weighted average price of the Company's common stock for the 30 trading days prior to the funding date for each tranche, or the Tranche B Warrant, and the Tranche C Warrant, respectively, and together the Additional Warrants. The Additional Warrants will be immediately exercisable upon issuance, and the exercise period will expire seven years from the date of issuance.

Cash Flows

The following table summarizes our sources and uses of cash, cash equivalents and restricted cash for the years ended December 31, 2023 and 2022.

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Cash used in operating activities	$ (117,354)	$ (228,816)
Cash provided by investing activities	$ 10,582	$ 82,428
Cash provided by financing activities	$ 71,705	$ 129,602
Net decrease in cash, cash equivalents and restricted cash	$ (35,067)	$ (16,786)

Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was $117.4 million, primarily due to a net loss of $113.7 million and changes in our operating assets and liabilities of $59.0 million, partially offset by non-cash charges of $55.3 million. Non-cash charges consisted of $34.1 million of stock-based compensation expense, loss sharing under the 2021 License Agreement with Nestlé of $5.2 million, $8.9 million related to the amortization of right-of-use assets, $6.2 million of depreciation, $0.9 million of net amortization of premiums related to our investments and amortization of debt issuance costs, and $1.6 million of loss from the extinguishment of the Hercules Credit Facility. These were partially offset by a $1.6 million decrease in the fair value of the Additional Warrants. Changes in our operating assets and liabilities during the year ended December 31, 2023 primarily consisted of a $29.1 million increase in prepaid expenses and other current and non-current assets, an increase in inventories of $29.6 million and an increase in collaboration receivable - related party of $8.7 million, as a result of the commencement of our commercial operations since the FDA approval of VOWST in April 2023, an $11.6 million decrease in accounts payable, a $1.3 million decrease in deferred revenue and a $2.2 million decrease in operating lease liabilities, partially offset by a $15.8 million increase in accrued

expenses and other liabilities and an increase in deferred income - related party of $7.7 million. The increase in prepaid expenses and other current and non-current assets and accrued expenses and other liabilities was primarily due to the achievement of the substantial completion milestone pursuant to the Bacthera Agreement. The decrease in deferred revenue was 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, 2022, net cash used in operating activities was $228.8 million, primarily due to a 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 was 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.

Investing Activities

During the year ended December 31, 2023, net cash provided by investing activities was $10.6 million, primarily due to maturities of investments of $23.0 million, partially offset by purchases of investments of $4.4 million and purchases of property and equipment of $8.0 million.

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.

Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities was $71.7 million, consisting of $103.4 million in proceeds from the issuance of the Oaktree Term Loan, offset by $52.9 million for the repayment of the Hercules Credit Facility. Cash provided by financing activities also consisted of $18.2 million from the issuance of common stock under our at the market equity program, net of issuance costs. We also received $0.9 million from the issuance of common stock associated with the exercise of stock options, and $2.2 million in connection with the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

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 ESPP. These cash inflows were partially offset by principal payments under the Original Credit Facility of $1.9 million.

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:

- advance commercialization of VOWST;
- 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 Restructuring Plan, including its anticipated benefits;
- 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 Hercules Loan Agreement included and our Oaktree Term Loan 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 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 issuances 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 we will require additional funding prior to the end of 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 November 2028 and April 2033. As of December 31, 2023, our contractual commitments for our leases were $177.4 million, of which $19.9 million is expected to be paid within one year, and $157.5 million will be paid over the remaining term of such leases. Our lease commitments also include $0.8 million for leases that had not yet commenced as of December 31, 2023. For additional information on our leases and timing of future payments, please read Note 8, *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 Oaktree total $14.4 million in interest-only payments through December 31, 2024. Our remaining commitments are due through April 2029, and include principal and interest payments of $153.3 million, and an additional fee upon maturity of the loan of $1.7 million. The interest rate in effect at December 31, 2023 was 12.875%. See Note 9, *Notes Payable*, to the consolidated financial statements for further discussion of the Oaktree Term Loan.

Bacthera Long Term Manufacturing Agreement

Our commitments due under the Bacthera Agreement, inclusive of construction fees and annual operating fees, total $288.8 million. Under the Bacthera Agreement $30.0 million was due upon substantial completion of our dedicated production suite, which occurred in late 2023, and remains unpaid, accruing interest in accordance with the Bacthera Agreement. The remaining construction milestones are approximately $12.6 million and $29.2 million, which will be due and payable upon provisional acceptance and final acceptance, respectively, and are expected to be due within the next 12 months. We have entered into negotiations with Bacthera to realign the timing of milestone payments. The Bacthera Agreement also includes $14.6 million in operating fees expected to be paid in the next year, with the remaining $202.3 million in operating fees paid over the remaining 9 years of the contract, beginning in 2025.

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, 2023, 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, 2023, we had outstanding borrowings under the Oaktree Term Loan. Borrowings under the Oaktree Term Loan bear interest at a rate per annum equal to three-month term Secured Overnight Financing Rate (subject to a 2.500% floor and a 5.000% cap), plus an applicable margin of 7.875%, payable quarterly in arrears. An immediate 10% change in the Secured Overnight Financing 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, 2023, 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, 2023, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. As we are a non-accelerated filer, management's report is not subject to attestation by our independent registered public accounting firm.

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

a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

None.

b) Insider Trading Arrangements and Policies.

During the three months ended December 31, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

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)	78	Director
Stephen Berenson (3)	63	Chairman of the Board of Directors
Paul R. Biondi (2)	54	Director
Willard H. Dere, M.D. (1)(4)	70	Director
Claire M. Fraser, Ph.D. (1)(4)	68	Director
Kurt C. Graves (2)	56	Director
Richard N. Kender (1)(2)	68	Director
Eric D. Shaff	48	President, Chief Executive Officer and 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 as Vice Chairman of the board of directors of Spexis AG, a clinical-stage biopharmaceutical company, since December 2021, 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.

Stephen A. 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 bioplatform 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 pharmaceutical company, since July 2021, and has served on the board of directors of Moderna, Inc., a pharmaceutical and biotechnology company, since October 2017. 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, a life sciences innovation firm which conceives, creates, resources and develops first-in-category bioplatform companies, 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, Mersana Therapeutics, Inc. since 2018, and Metagenomi, Inc. since August 2021, 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, a medical technology 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 Chairman, President and Chief Executive Officer of i20 Therapeutics, Inc., a biotechnology company, since August 2023, and he previously served as the Executive Chairman of its board of directors from August 2021 to August 2023. 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 senior leadership positions at Novartis Pharmaceuticals Corporation, or Novartis Corp., from 1999 to June 2007, including the Global General Medicines Business Unit Head and Global Chief Marketing Officer for the pharmaceuticals division of Novartis Corp. from September 2003 to June 2007. Prior to Novartis Corp., Mr. Graves held senior leadership positions at Merck and Astra-Merck where he led the U.S. Business Unit responsible for Prilosec, Nexium and Prilosec OTC over a 10-year period. He served as Chairman on the board of directors of Radius Health, Inc. from May 2011 to March 2020, and as a director on Achillion Pharmaceuticals, Inc., or Achillion, from June 2012 to January 2020, when Achillion was acquired. 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., a clinical stage biopharmaceutical company, since March 2015 and Bicycle Therapeutics PLC since July 2019. He previously served on the boards of directors of INC Research Holdings, Inc. (now known as Syneos Health) 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 previously served on the board of directors of Sigilon Therapeutics, Inc. from 2017 to August 2023. 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.

Information about our Executive Officers

Name	Age	Position
Eric D. Shaff[1][2]	48	President, Chief Executive Officer and Director
David Arkowitz[2]	62	Executive Vice President, Chief Financial Officer and Head of Business Development
Thomas J. DesRosier	69	Executive Vice President and Chief Legal Officer
David S. Ege, Ph.D.	49	Executive Vice President and Chief Technology Officer
Matthew Henn, Ph.D.	49	Executive Vice President and Chief Scientific Officer
Lisa von Moltke, M.D.	65	Executive Vice President and Chief Medical Officer
Teresa L. Young, Ph.D.	57	Executive Vice President, Chief Commercial and Strategy Officer

(1) Information concerning Eric D. Shaff, our President and Chief Executive Officer, may be found above in the section entitled "Director Biographical Information."
(2) On February 26, 2024, the Company announced that David Arkowitz is retiring as Executive Vice President, Chief Financial Officer and Head of Business Development, principal financial officer and principal accounting officer of the Company, effective as of March 15, 2024. Effective as of Mr. Arkowitz's retirement, the Board has designated Eric Shaff to serve as the Company's interim principal financial officer and interim principal accounting officer until the expected commencement of employment of Marella Thorell as the Company's Executive Vice President and Chief Financial Officer, principal financial officer, and principal accounting officer on or about March 25, 2024.

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 currently serves on the board of directors of Kineta, Inc., and has previously served on the boards of directors of F-star Therapeutics, Inc., 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.

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. He has been involved in the discovery and development of multiple microbiome therapeutics across infectious, inflammatory, and oncology indications, and has authored over 75 peer-reviewed publications. His research has focused on microbial populations and the functional role of microbes in both environmental and human disease applications, and the development of genomic and functional technologies to study these populations. Prior to participating in the launch of our company in 2012, he was the Director of Viral Genomics and Assistant Director of the Genome Sequencing Center for Infectious Diseases at the Broad Institute of Massachusetts Institute of Technology and Harvard. He has served on various National Institutes of Health, or NIH, working groups on antimicrobial resistance and microbiome research, as a scientific advisor for NIH's Viral Pathogen Bioinformatics Resource Center, as an ad-hoc reviewer and editor of various peer-reviewed journals, and as a scientific advisor to non-profit and for-profit organizations. He currently serves on the Microbiome Therapeutics Innovation Group board of directors, the World Microbiome Partnership steering

committee, Life Sciences Cares board of advisors, and the scientific advisory board of Growcentia, Inc., an agricultural microbiome company. Dr. Henn is formally trained in ecology and evolutionary biology and earned 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 2024 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 2024 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 2024 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 2024 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 2024 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	Certificate of Amendment to Restated Certificate of Incorporation of Registrant, dated June 27, 2023	8-K	001-37465	3.1	6/28/23	
3.3	Amended and Restated Bylaws	8-K	001-37465	3.1	1/2/24	
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					*
4.3	Form of Warrant, dated April 27, 2023, issued by the Registrant to the Lenders, together with a schedule of warrant holders	8-K	001-37465	4.1	4/27/23	
10.1#	2015 Incentive Award Plan, as amended and forms of award agreements thereunder	10-K	001-37465	10.1	3/7/23	
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-K	001-37465	10.4	3/7/23	
10.5#	Non-Employee Director Compensation Program	10-K	001-37465	10.5	3/7/23	
10.6	Lease, dated September 22, 2021, by and between the Registrant and HCP/KING 101 CPD LLC					*
10.7#	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	
10.8#	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	
10.9#	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	
10.10#	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	
10.11#	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	

10.12#	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	
10.13#	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	
10.14#	Employment Agreement, dated May 10, 2021 by and between the Registrant and David Arkowitz	8-K	001-37465	10.1	5/20/21	
10.15^	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	
10.16	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	
10.17^	Letter Agreement dated October 30, 2018, by and between the Registrant and Nestec Ltd.	10-K	001-37465	10.23	3/6/19	
10.18	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	
10.19†	License Agreement, dated July 1, 2021, by and between the Registrant and NHSc Pharma Partners	10-Q	001-37465	10.1	11/10/21	
10.20†	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	
10.21†	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	
10.22†	Amendment to Long Term Manufacturing Agreement, dated December 14, 2022, by and between the Registrant and BacThera AG	10-K	001-37465	10.28	3/7/23	
10.23	Form of Non-Affiliate Purchase Agreement	8-K	001-37465	10.1	6/30/22	
10.24	Form of Affiliate Purchase Agreement	8-K	001-37465	10.2	6/30/22	
10.25	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	
10.26†	Supply Agreement, dated September 15, 2015, by and between Registrant and GenIbet BioPharmaceuticals, SA, as amended					*
10.27†	Supply Agreement, dated March 13, 2023, by and between the Registrant and Nestlé Enterprises S.A.	10-Q	001-37465	10.1	5/9/23	
10.28	Credit Agreement and Guaranty, dated April 27, 2023, among the Registrant, as the borrower, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent for the lenders	8-K	001-37465	10.1	4/27/23	
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	**
97.1#	Policy for Recovery of Erroneously Awarded Compensation	*
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	*
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 5, 2024

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 5, 2024
/s/ David Arkowitz David Arkowitz	Executive Vice President, Chief Financial Officer, and Head of Business Development (Principal Financial and Accounting Officer)	March 5, 2024
/s/ Stephen Berenson Stephen Berenson	Chairman of the Board	March 5, 2024
/s/ Dennis A. Ausiello Dennis A. Ausiello, M.D.	Director	March 5, 2024
/s/ Paul R. Biondi Paul R. Biondi	Director	March 5, 2024
/s/ Willard H. Dere Willard H. Dere, M.D.	Director	March 5, 2024
/s/ Claire M. Fraser Claire M. Fraser, Ph.D.	Director	March 5, 2024
/s/ Kurt C. Graves Kurt C. Graves	Director	March 5, 2024
/s/ Richard N. Kender Richard N. Kender	Director	March 5, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Seres Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, of stockholders' (deficit) equity and of cash flows for each of the three years in the period ended December 31, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America.

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 Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements 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 of these consolidated financial statements 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

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.

Recognition of Collaboration (Profit) Loss Sharing - License Agreement with NHSc Rx License GmbH (Nestlé)

As described in Note 15 to the consolidated financial statements, the Company recognizes collaboration (profit) loss sharing – related party arising from a license agreement with Nestlé, which totaled $0.7 million for the year ended December 31, 2023. Under the 2021 License Agreement with Nestlé, beginning with the first commercial sale of VOWST, which occurred in June 2023, net sales of VOWST are recorded by Nestlé. The Company records its share of the profits or losses from the sales of VOWST, including commercial and medical affairs expenses incurred by the Company, on a net basis, as collaboration (profit) loss sharing - related party. The collaboration (profit) loss sharing - related party line item also includes the Company's profit on the transfer of VOWST inventory

to Nestlé, which represents the excess of the supply price paid by Nestlé over the Company's cost to manufacture VOWST, subject to a supply price cap applicable to product manufactured prior to commercial launch.

The principal consideration for our determination that performing procedures relating to the recognition of collaboration (profit) loss sharing arising from the license agreement with Nestlé is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's recognition of collaboration (profit) loss sharing.

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, among others (i) evaluating management's collaboration (profit) loss sharing accounting policy; (ii) testing the completeness and accuracy of certain data used to calculate the collaboration (profit) loss sharing by sending a confirmation and obtaining and inspecting source documents provided by Nestlé; (iii) recalculating the Company's share of the profit or losses from the sales of VOWST; and (iv) recalculating the Company's profit on transfer of VOWST inventory to Nestlé and obtaining and inspecting source documents, such as invoices and evidence of payment.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 5, 2024

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,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 127,965	$ 163,030
Short term investments	—	18,311
Collaboration receivable - related party	8,674	—
Inventories	29,647	—
Prepaid expenses and other current assets	9,124	13,423
Total current assets	175,410	194,764
Property and equipment, net	22,457	22,985
Operating lease assets	109,793	110,984
Restricted cash	8,185	8,185
Restricted investments	1,401	1,401
Other non-current assets (1)	41,354	10,465
Total assets	$ 358,600	$ 348,784
Liabilities and Stockholder's Equity		
Current liabilities:		
Accounts payable	$ 3,641	$ 17,440
Accrued expenses and other current liabilities (2)	80,611	59,840
Operating lease liabilities	6,677	3,601
Short term portion of note payable, net of discount	—	456
Deferred income - related party	7,730	—
Deferred revenue - related party	—	4,259
Total current liabilities	98,659	85,596
Long term portion of note payable, net of discount	101,544	50,591
Operating lease liabilities, net of current portion	105,715	107,942
Deferred revenue, net of current portion - related party	95,364	92,430
Warrant liability	546	—
Other long-term liabilities	1,628	1,442
Total liabilities	403,456	338,001
Commitments and contingencies (Note 16)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.001 par value; 240,000,000 and 200,000,000 shares authorized at December 31, 2023 and 2022, respectively; 135,041,467 and 125,222,273 shares issued and outstanding at December 31, 2023 and 2022, respectively	135	125
Additional paid-in capital	933,244	875,181
Accumulated other comprehensive loss	—	(12)
Accumulated deficit	(978,235)	(864,511)
Total stockholders' (deficit) equity	(44,856)	10,783
Total liabilities and stockholders' equity	$ 358,600	$ 348,784

[1] Includes $38,877 and $8,828 as of December 31, 2023 and December 31, 2022, respectively, of milestones related to the construction of the Company's dedicated manufacturing suite at BacThera AG, or Bacthera (see Note 16, *Commitments and Contingencies*). Such amounts will form part of the right-of-use asset upon lease commencement.

[2] Includes related party amounts of $28,053 and $34,770 at December 31, 2023 and December 31, 2022, respectively (see Note 18)

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,		
	2023	2022	2021
Revenue:			
Collaboration revenue - related party	$ 126,325	$ 7,128	$ 143,857
Grant revenue	—	—	1,070
Total revenue	126,325	7,128	144,927
Operating expenses:			
Research and development expenses	$ 145,860	$ 172,920	$ 141,891
General and administrative expenses	87,744	79,694	69,261
Collaboration (profit) loss sharing - related party	704	1,004	(1,732)
Total operating expenses	234,308	253,618	209,420
Loss from operations	(107,983)	(246,490)	(64,493)
Other (expense) income:			
Interest income	7,301	3,058	2,870
Interest expense	(13,176)	(6,020)	(2,910)
Other income (expense)	134	(705)	(1,045)
Total other (expense) income, net	(5,741)	(3,667)	(1,085)
Net loss	$ (113,724)	$ (250,157)	$ (65,578)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.89)	$ (2.31)	$ (0.72)
Weighted average common shares outstanding, basic and diluted	128,003,294	108,077,043	91,702,866
Other comprehensive income (loss):			
Unrealized gain (loss) on investments, net of tax of $0	10	49	(12)
Currency translation adjustment	2	(1)	(1)
Total other comprehensive income (loss)	12	48	(13)
Comprehensive loss	$ (113,712)	$ (250,109)	$ (65,591)

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

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

	Common Stock		Additional	Accumulated Other		Total
	Shares	Par Value	Paid-in Capital	Comprehensive Loss (Income)	Accumulated Deficit	Stockholders (Deficit) Equity
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	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 income	—	—	—	48	—	48
Net loss	—	—	—	—	(250,157)	(250,157)
Balance at December 31, 2022	125,222,273	125	875,181	(12)	(864,511)	10,783
Issuance of common stock upon exercise of stock options	260,640	—	877	—	—	877
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	1,244,663	1	(1)	—	—	—
Issuance of common stock under ESPP	602,692	2	2,149	—	—	2,151
Issuance of common stock from at the market equity offering, net of issuance costs of $772	7,711,199	7	18,152	—	—	18,159
Issuance of warrants	—	—	2,785	—	—	2,785
Stock-based compensation expense	—	—	34,101	—	—	34,101
Other comprehensive income	—	—	—	12	—	12
Net loss	—	—	—	—	(113,724)	(113,724)
Balance at December 31, 2023	135,041,467	$ 135	$ 933,244	$ —	$ (978,235)	$ (44,856)

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,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (113,724)	$ (250,157)	$ (65,578)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation expense	34,101	25,482	20,222
Depreciation and amortization expense	6,243	6,629	5,947
Non-cash operating lease cost	8,871	5,224	3,275
Amortization of premiums on investments	(236)	688	498
Amortization of debt issuance costs	1,139	705	2,526
Loss on extinguishment of debt	1,625	—	—
Change in fair value of warrant liabilities	(1,554)	—	—
Collaboration (profit) loss sharing - related party	5,158	1,004	(1,732)
Changes in operating assets and liabilities:			
Prepaid expenses and other current and non-current assets	(29,124)	(12,599)	(12,337)
Collaboration receivable - related party	(8,674)	—	—
Inventories	(29,647)	—	—
Accounts receivable	—	—	9,387
Deferred income - related party	7,730	—	—
Deferred revenue - related party	(1,325)	(7,128)	(4,357)
Accounts payable	(11,578)	2,203	9,362
Operating lease liabilities	(2,197)	(4,203)	(3,550)
Accrued expenses and other current and long-term liabilities (3)	15,838	3,336	43,025
Net cash (used in) provided by operating activities	(117,354)	(228,816)	6,688
Cash flows from investing activities:			
Purchases of property and equipment	(7,975)	(9,821)	(9,566)
Purchases of investments	(4,426)	(48,221)	(95,971)
Sales and maturities of investments	22,983	140,470	169,625
Net cash provided by investing activities	10,582	82,428	64,088
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of issuance costs	—	96,721	—
Proceeds from at the market equity offering, net of issuance costs	18,159	4,447	—
Proceeds from exercise of stock options	877	966	1,299
Issuance of common stock under ESPP	2,151	1,769	827
Proceeds from issuance of debt, net of issuance costs	103,378	27,606	—
Repayment of notes payable	(52,860)	(1,907)	(948)
Net cash provided by financing activities	71,705	129,602	1,178
Net (decrease) increase in cash, cash equivalents and restricted cash	(35,067)	(16,786)	71,954
Effect of exchange rate changes on cash, cash equivalents and restricted cash	2	(1)	(1)
Cash, cash equivalents and restricted cash at beginning of year	171,215	188,002	116,049
Cash, cash equivalents and restricted cash at end of year	$ 136,150	$ 171,215	$ 188,002
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 12,547	$ 4,926	$ 2,446
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment purchases included in accounts payable and accrued expenses	$ 16	$ 2,276	$ 874
Lease liability arising from obtaining right-of-use assets	$ 3,046	$ 91,412	$ 12,442
Prepaid rent reclassified to right-of-use assets	$ 4,634	$ 6,822	$ —
Recognition of warrant liabilities	$ 2,100	$ —	$ —
Warrants issued related to Term Loan and recorded as debt discount (Note 9)	$ 2,785	$ —	$ —

[3] Includes related party amounts of $(6,717), $3,087, and $31,683 at December 31, 2023, 2022, and 2021, respectively (see Note 18)

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

SERES THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a commercial-stage microbiome therapeutics company focused on the development and commercialization of 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 product, VOWST (fecal microbiota spores, live brkp), formerly called SER-109, was approved by the U.S. Food and Drug Administration ("FDA") on April 26, 2023 and is the first and only orally administered microbiome therapeutic. VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection ("CDI") in patients 18 or older following antibacterial treatment for recurrent CDI. The Company launched VOWST in the United States with its collaborator, Nestlé Health Science ("Nestlé"), in June 2023.

Building upon VOWST, the Company is progressing the Phase 1b clinical trial of SER-155, a microbiome therapeutic candidate consisting of a 16-strain consortium of cultivated bacteria designed to prevent enteric-derived infections and resulting bloodstream infections, as well as induce immune tolerance responses to reduce the incidence of graft-versus-host disease ("GvHD") in patients undergoing allogeneic hematopoietic stem cell transplantation ("allo-HSCT"). Gastrointestinal microbiome data from the first 100 days of SER-155 Phase 1b open-label study cohort 1 showed the successful engraftment of SER-155 bacterial strains, and a substantial reduction in the cumulative incidence of pathogen domination as compared to a reference cohort of patients, a biomarker associated with the risk of serious enteric infections and resulting bloodstream infections, as well as GvHD. The tolerability profile observed was favorable, with no serious adverse events attributed to SER-155 administration. Enrollment in the placebo-controlled cohort 2 portion of the study is ongoing, and the cohort 2 data readout is anticipated in the third quarter of 2024.

The Company has built and deploys a reverse translational platform and knowledge base for the discovery and development of microbiome therapeutics, and maintains extensive proprietary know-how that may be used to support future research and development efforts. 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. In addition, the Company owns a valuable intellectual property estate related to the development and manufacture of microbiome therapeutics.

On October 29, 2023, the Company's Board of Directors approved a restructuring plan to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while significantly reducing costs and supporting longer-term business sustainability (the "Restructuring Plan"). The Restructuring Plan included (i) a reduction of the Company's workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space. For additional information on the Restructuring Plan, see Note 13, *Restructuring*.

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 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, 2023, the Company had an accumulated deficit of $978,235 and cash and cash equivalents of $127,965.

The Company's primary focus in recent months has been and will continue to be supporting commercialization, including the manufacture of VOWST, and the completion of the SER-155 Phase 1b study, which requires capital and resources. Other than VOWST, the Company's product candidates are in development, and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to potential commercialization. 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.

Primarily as a result of the increased and costly efforts to commercialize VOWST and to continue the research and development efforts for other product candidates and preclinical programs, for the year ended December 31, 2023, the Company incurred a net loss of $113,724, and had net operating cash outflows of $117,354. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. 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, the Company will require additional funding to maintain commercial production of VOWST, continue to progress the SER-155 Phase 1b study, and meet its operational obligations as they come due. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due, and to generate profitable operations in the future. Management plans to provide for the Company's capital requirements through financing or other transactions, including drawing the Tranche B Term Loan pursuant to the Oaktree Credit Agreement (see Note 9, *Notes Payable*), which is expected to become available to the Company based on VOWST net sales forecasts assuming continued quarter-over-quarter net sales growth, and selling shares under the Company's at the market equity offering. There can be no assurance that the Company will generate significant profit from the transfer of VOWST to Nestlé or its share of collaboration profits resulting from net sales of VOWST, or that it will be able to raise additional capital to fund operations with terms acceptable to the Company, or at all. Because certain elements of management's plans to mitigate the conditions that raised substantial doubt about the Company's ability to continue as a going concern are outside of the Company's control, including 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, the Company expects to sell the security prior to the recovery of its unrealized losses, or it is more likely than not that the Company will be required to sell the security prior to the recovery of its amortized cost basis. When determining whether a credit loss exists, the Company considers several factors, including the estimated present value of expected cash flows from the security, whether the Company has the intent to sell the security or whether it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis. If the Company has an intent to sell, or if it is more likely than not that the Company will be required to sell a debt security in an unrealized loss position before recovery of its amortized cost basis, the Company will write down the security to its fair value and record the corresponding 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, 2023, 2022, and 2021.

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, 2023 and 2022, 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 as of December 31, 2023 and 2022, 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,	
	2023	2022
Cash and cash equivalents	$ 127,965	$ 163,030
Restricted cash, non-current	8,185	8,185
Total cash, cash equivalents and restricted cash	$ 136,150	$ 171,215

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. The warrant liabilities associated with the Company's credit facility with Oaktree for which there is no current market and the determination of fair value requires significant estimation are classified as Level 3 financial liabilities.

Inventories

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in first-out method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials.

Prior to the regulatory approval of its product candidates, the Company incurs expenses for the manufacture of drug product supplies to support clinical development that could potentially be available to support the commercial launch of those drugs. Until the date at which regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expenses.

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 or asset group 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 or asset group 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 based on reporting provided by third parties, typically contract research organizations. 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

The Company analyzes its 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, the Company first determines 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, the Company applies 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. The Company records its share of the profits or losses from the sales of VOWST on a net basis, as collaboration (profit) loss sharing - related party because Nestlé and the Company are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the arrangement. The collaboration (profit) loss sharing - related party line item also includes the Company's profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over our cost to manufacture VOWST.

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, 2023, 2022 and 2021, 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 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 Accounting Standards Update ("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. 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

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures,* which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280, on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 may have on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its consolidated 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, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 81	$ —	$ —	$ 81
Commercial paper	—	—	—	—
Government securities	—	—	—	—
Total assets	$ 81	$ —	$ —	$ 81
Warrant liabilities	$ —	$ —	$ 546	$ 546
Total liabilities	$ —	$ —	$ 546	$ 546

	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
Certificate of deposits	—	—	—	—
Government securities	—	12,889	—	12,889
	$ 47,863	$ 34,968	$ —	$ 82,831

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.

As of December 31, 2023 and 2022 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.

Level 3 financial liabilities consist of the warrant liabilities for which there is no current market such that the determination of fair value requires significant judgment or estimation. Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded through other income (expense). The Company uses a Monte-Carlo simulation model which includes the Black-Scholes option pricing model to value the Level 3 warrant liabilities at inception and on each subsequent reporting date. This model incorporates transaction details such as the Company's stock price, contractual terms of the underlying warrants, maturity, risk free rates, volatility, as well as the term to achievement of estimated sales targets. The unobservable inputs for all of the Level 3 warrant liabilities are volatility and the term to achievement of estimated sales targets. The Company utilizes its historical and implied volatility, using its closing common stock prices and market data, to reflect future volatility over the expected term of the warrants. The Company estimates the time to achievement of sales targets of VOWST using information and forecasts generated by the Company in consideration of the terms of the 2021 License Agreement.

On the Closing Date (as defined in Note 9, *Notes Payable*) and as of December 31, 2023, the Level 3 inputs to the warrant liabilities are as follows:

	Closing Date	December 31, 2023
Volatility	83.0%	101.0%
Term (in years)	1.7	1.3

A reconciliation of the beginning and ending balances for the year ended December 31, 2023 for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	Warrant Liabilities
Balance as of December 31, 2022	$ —
Issuance of warrants	2,100
Adjustment to fair value	(1,554)
Balance as of December 31, 2023	546

There were no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the year ended December 31, 2022. There were no transfers between Level 1, Level 2, or Level 3 during the years ended December 31, 2023 and 2022.

4. Investments

As of December 31, 2023, the Company held restricted investments of $1,401, the cost of which approximates current fair value. The Company did not hold any other investments as of December 31, 2023.

Investments by security type consisted of the following at December 31, 2022 (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

Excluded from the table above at December 31, 2022 are restricted investments of $1,401, as the cost approximates current fair value. 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. As of December 31, 2022, all of the Company's investments were classified as available-for-sale and matured within 12 months of the balance sheet date.

5. Inventories

Capitalized inventories consist of the following at December 31, 2023 (in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$ 4,426	$ —
Work in process	25,221	—
Finished goods	—	—
Total	$ 29,647	$ —

There were no inventories capitalized as of December 31, 2022, because the Company obtained approval for VOWST from the FDA on April 26, 2023. Prior to this approval, all costs for the manufacture of product supplies to support clinical development and commercial launch, including pre-launch inventory, were expensed as incurred or otherwise accounted for pursuant to the 2021 License Agreement. Pre-launch inventory manufactured prior to the FDA approval of VOWST, which was not capitalized into inventory but instead was expensed as research and development in previous periods, will be used in commercial production until it is depleted. Pre-launch inventory expensed as research and development totaled $26,794 for the year ended December 31, 2023.

Inventory amounts written down as a result of excess, obsolescence, or unmarketability and determined not to be recoverable pursuant to the 2021 License Agreement are expensed in the period in which they are identified. There were no such write-downs during the year ended December 31, 2023.

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2023	2022
Laboratory equipment	$ 29,081	$ 24,533
Computer equipment	4,142	3,557
Furniture and office equipment	5,430	3,491
Leasehold improvements	33,549	32,474
Construction in progress	1,393	3,970
	73,595	68,025
Less: Accumulated depreciation and amortization	(51,138)	(45,040)
	$ 22,457	$ 22,985

Depreciation and amortization expense was $6,243, $6,629 and $5,947 for the years ended December 31, 2023, 2022 and 2021, respectively. During the years ended December 31, 2023 and 2022, the Company disposed of certain fully-depreciated assets with a cost basis of $145 and $1,857, respectively.

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

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2023	2022
Clinical and development costs	$ 1,404	$ 6,717
Manufacturing and quality costs	31,917	—
Payroll and payroll-related costs	16,465	14,709
Collaboration payable - related party (Note 18)	28,053	34,770
Facility and other	2,772	3,644
	$ 80,611	$ 59,840

As of December 31, 2023, the Company accrued a total of $30,049 payable to Bacthera for the substantial completion of the Company's dedicated production suite for long-term supply of VOWST, as the milestone was achieved during the year ended December 31, 2023. This amount is included in the Manufacturing and quality costs category above.

Additionally, included within payroll and payroll-related costs is $5,080 of accrued severance related to the Restructuring Plan. See Note 13, *Restructuring*, for further details.

8. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from approximately one to nine 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 ten 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 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 were $3,029, net of a tenant improvement allowance of $1,184, over the original ten-year term. The lease commenced in April 2023. For the year ended December 31, 2023, the Company recorded a right-of-use asset of $3,571, which consists of the lease liability of $1,235, and $2,336 of leasehold improvements that revert back to the lessor at the termination of the lease.

In December 2022, the Company amended its lease of its former 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 an estimated 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.

In June 2023, the Company entered into a lease for a donor collection facility in Irvine, California, with a lease term of approximately six years and a renewal option, subject to certain conditions, for an additional five-year term. The undiscounted minimum lease payments are $1,079 over the original term. The lease commenced in December 2023. For the year ended December 31, 2023, the Company recorded a right-of-use asset of $1,830, which consists of the lease liability of $768, and $1,062 of leasehold improvements that revert back to the lessor at the termination of the lease.

In January 2024, the Company entered into a sublease agreement with an unrelated third party to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in March 2024 and ends on January 13, 2030. The Company will receive lease payments over the sublease term totaling $10,400. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management.

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

	December 31,	
	2023	2022
Assets:		
Operating lease assets	$ 109,793	$ 110,984
Liabilities:		
Operating lease liabilities	$ 6,677	$ 3,601
Operating lease liabilities, net of current portion	105,715	107,942
Total operating lease liabilities	$ 112,392	$ 111,543

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

	Year Ended December 31,		
	2023	2022	2021
Operating lease costs	$ 22,324	$ 8,830	$ 5,170
Short-term lease costs	1,477	1,375	1,452
Variable lease costs	7,229	4,547	3,300
Sublease income	—	—	(1,575)
Total lease costs	$ 31,030	$ 14,752	$ 8,347

During the years ended December 31, 2023, 2022, and 2021, the Company made cash payments for operating leases of $15,656, $7,809 and $6,821, respectively.

As of December 31, 2023, future payments of operating lease liabilities are as follows (in thousands):

	As of December 31, 2023
2024	$ 19,869
2025	22,062
2026	22,674
2027	23,347
2028	23,580
2029 and thereafter	65,819
Total future payments of operating lease liabilities	$ 177,351
Less: imputed interest	(64,959)
Present value of operating lease liabilities	$ 112,392

As of December 31, 2023, the weighted average remaining lease term was 7.95 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. 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%.

9. Notes Payable

On October 29, 2019 ("Hercules Closing Date"), the Company entered into a Loan and Security Agreement (the "Hercules Loan Agreement") with Hercules Capital, Inc. ("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. Effective as of February 24, 2022 (the "Effective Date"), the Company entered into an Amendment to the Hercules Loan Agreement (the "Amendment"), with the lenders party thereto (the "Hercules Lenders"), and Hercules in its capacity as the administrative agent and the collateral agent for the Hercules Lenders, which amended the Original Credit Facility. Pursuant to the Amendment, a term loan facility in an amount of $100,000 (the "Hercules Credit Facility") became available to the Company in five tranches, including the first tranche of $25,000 previously drawn under the Original Credit Facility, 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 were advanced to the Company and were outstanding as of the Effective Date. The fourth and fifth tranches, in an aggregate principal amounts of $25,000 each, were available upon satisfaction of certain conditions, but were not drawn before the repayment and extinguishment of the Hercules Credit Facility.

All advances outstanding under the Hercules Credit Facility bore interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 6.40%, or (ii) 9.65%. The Company had the option to prepay advances under the Hercules Credit Facility, in whole or in part, at any time subject to a prepayment charge, and the Hercules Loan Agreement included an end of term charge of 4.85% of the aggregate amount of the advances made under the Original Credit Facility, as well as an additional end of term charge of 1.75% of the aggregate amount of the advances under the Hercules Credit Facility (including the first tranche of $25,000), each due as specified in the Amendment.

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

The Company accounted for the Amendment as a modification in accordance with the guidance in ASC 470-50, *Debt* ("ASC 470"). Amounts paid to the lenders were recorded as debt discount and a new effective interest rate was established. Upon issuance, the Hercules Credit Facility was recorded as a liability with an initial carrying value of $50,586, net of debt issuance costs. The initial carrying value was 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 debt. As of December 31, 2022, the carrying value of the debt was $51,047.

On April 27, 2023 (the "Closing Date"), the Company entered into the Credit Agreement and Guaranty (the "Oaktree Credit Agreement") among the Company, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto (the "Lenders"), and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Lenders (in such capacity, the "Agent"). The Oaktree Credit Agreement establishes a term loan facility of $250,000 (the "Term Loan") consisting of (i) $80,000 ("Tranche A-1") and (ii) $30,000 ("Tranche A-2" and collectively, "Tranche A Loan"), funded on the Closing Date. The Term Loan also consists of (i) $45,000 (the "Tranche B Loan") and (iii) $45,000 (the "Tranche C Loan"), each of which the Company may borrow subject to certain conditions, and (iv) $50,000 (the "Tranche D Loan") available in Oaktree's sole discretion. The Tranche B Loan may be drawn by the Company until September 30, 2024, if VOWST net sales for the trailing six consecutive months are at least $35,000 and at least 4.5% greater in the calendar quarter prior to the Applicable Funding Date (as defined in the Oaktree Credit Agreement) over the calendar quarter immediately preceding it. The Tranche C Loan may be drawn until September 30, 2025, if VOWST net sales for the trailing 12 consecutive months are at least $120,000 and at least 4.5% greater in each of the two calendar quarters prior to the Applicable Funding Date relative, in each case, to the calendar quarter immediately preceding it. The Term Loan has a maturity date of April 27, 2029 (the "Maturity Date").

Of the $110,000 Tranche A Loan advanced by the Lenders at closing, approximately $53,380 repaid the Company's existing credit facility with Hercules. After deducting other transaction expenses and fees, the Company received net proceeds of approximately $50,446. The Company accounted for the repayment of the Hercules Credit Facility as an extinguishment in accordance with the guidance in ASC 470-50, and recognized a loss on extinguishment of $1,625 in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

Borrowings under the Term Loan bear interest at a rate per annum equal to the three-month term Secured Overnight Financing Rate ("SOFR") (subject to a 2.50% floor and a 5.00% cap), plus an applicable margin of 7.875%, payable quarterly in arrears. If certain VOWST net sales targets are met, the applicable margin will be reduced from 7.875% to 7.50% through the Maturity Date. The Company is required to make quarterly interest-only payments on the Term Loan for the first three years after the Closing Date. Beginning on June 30, 2026, the Company will be required to make quarterly payments of interest, plus repay 7.50% of the outstanding principal of the Term Loan in quarterly installments until the Maturity Date, unless the interest only period is extended based upon the achievement of certain VOWST net sales targets.

The Company is obligated to pay the Lenders an exit fee equal to 1.50% of the aggregate amount of the Term Loan funded, such exit fee to be due and payable upon the earliest to occur of (1) the Maturity Date, (2) the acceleration of the outstanding Term Loan, and (3) the prepayment of the outstanding Term Loan. The Company may voluntarily prepay the outstanding Term Loan, subject to a customary make-whole for the first two years following the Closing Date plus 4.0% of the principal amount of the Term Loan prepaid, and thereafter a prepayment premium equal to (i) 4.0% of the principal amount of the Term Loan prepaid, if prepaid after the second anniversary of the Closing Date through and including the third anniversary of the Closing Date, (ii) 2.0% of the principal amount of the Term Loan if prepaid after the third anniversary of the Closing Date through and including the fourth anniversary of the Closing Date, (iii) 1.0% of the principal amount of the Term Loan if prepaid after the fourth anniversary of the Closing Date through and

including the fifth anniversary of the Closing Date, with no prepayment premium due after the fifth anniversary of the Closing Date through the Maturity Date.

The Company's obligations under the Oaktree Credit Agreement and the other Loan Documents (as defined in the Oaktree Credit Agreement) will be guaranteed by any domestic subsidiaries of the Company that become Guarantors (as defined in the Oaktree Credit Agreement), subject to certain exceptions. The Company's and the Guarantors' (collectively, the "Loan Parties") respective obligations under the Oaktree Credit Agreement and the other Loan Documents are secured by first priority security interests in substantially all assets of the Loan Parties, including intellectual property, subject to certain customary thresholds and exceptions. As of December 31, 2023, there were no Guarantors.

The Oaktree Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of the Agent of at least $30,000 at all times commencing from 30 days after the Closing Date and decreasing to $25,000 of cash and cash equivalents in such controlled accounts after the Company borrows any Tranche B Loan. As of December 31, 2023, the Company was in compliance with all financial covenants pursuant to the Oaktree Credit Agreement.

In addition, the Oaktree Credit Agreement contains certain events of default that entitle the Agent to cause the Company's indebtedness under the Oaktree Credit Agreement to become immediately due and payable, and to exercise remedies against the Loan Parties and the collateral securing the Term Loan, including cash. In an event of default and for its duration, as defined in the Oaktree Credit Agreement, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Oaktree Credit Agreement.

On the Closing Date, the Company issued to the Lenders warrants to purchase 647,589 shares (subject to certain adjustments) of the Company's common stock (the "Tranche A Warrant"), at an exercise price per share of $6.69. The Tranche A Warrant is immediately exercisable and the exercise period expires on April 26, 2030. Upon the funding of each of the Tranche B Loan and the Tranche C Loan, the Company is required to issue to the Lenders warrants to purchase 264,922 shares (subject to certain adjustments) of the Company's common stock on each such funding date at an exercise price equal to the trailing volume weighted average price of the Company's common stock for the 30 trading days prior to the funding date for each tranche (the "Tranche B Warrant" and the "Tranche C Warrant," respectively, and together the "Additional Warrants"). The Additional Warrants will be immediately exercisable upon issuance, and the exercise period will expire seven years from the date of issuance.

The Company determined that the Tranche A Loan, the Tranche A Warrant, the commitment by the Lenders to fund the Tranche B Loan and the Tranche C Loan, and the Tranche B Warrant and Tranche C Warrant, are all freestanding financial instruments. On the Closing Date, the Company evaluated the Tranche A Warrant and determined that it meets the requirements for equity classification under ASC 815, Derivatives and Hedging ("ASC 815"). The net proceeds from the Tranche A Loan were allocated to the Tranche A Warrant and the Tranche A Loan using the relative fair value method, and the relative fair value of the Tranche A Warrant, $2,785, is recorded as an increase to additional paid-in-capital on the consolidated statements of stockholder's equity (deficit), and as a discount to the Tranche A Loan that will be amortized over the life of the Tranche A Loan using the effective interest method. The Company used the Black-Scholes option pricing model to determine the fair value of the Tranche A Warrant. Assumptions used in the Black-Scholes model included the fair market value per share of common stock on the valuation date of $5.32, the exercise price per warrant equal to $6.69, the expected volatility of 111.6%, the risk-free interest rate of 3.57%, the expected term of 7 years and the absence of a dividend.

The Additional Warrants are considered outstanding instruments at the Closing Date of the Oaktree Credit Agreement and in accordance with ASC 815, are initially recognized at their respective fair values as derivative liabilities given the variable settlement amount of their respective aggregate exercise prices. The Company adjusts the carrying values of the Additional Warrants to their respective fair values at each reporting period, until such time that the Additional Warrants are issued and their respective exercise prices become fixed, and the value of the Additional Warrants is reclassified to additional paid-in capital. The Company uses a simulation model to determine the fair value of the Additional Warrants, as described in Note 3, Fair Value Measurements. The fair value of the Tranche B Warrant and Tranche C Warrant derivative liabilities was $1,077, $1,023, $276, and $270 on the Closing Date and at December 31, 2023, respectively.

Changes in the fair values of the Additional Warrants are recorded as other income (expense) in the consolidated statements of operations and comprehensive loss. In addition to the relative fair value of the Tranche A Warrant, the original issue discount and certain debt issuance costs were recorded as a discount to the Tranche A Loan, the total of which will be accreted to the Tranche A Loan as interest expense over the life of the Tranche A Loan using the effective interest method. The fair values of the derivative liabilities associated with the Tranche B Warrant and Tranche C Warrant are recorded as loan commitment prepaid assets on the Closing Date,

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

which are included in the consolidated balance sheets in other non-current assets, and will be reclassified as discounts to the associated Term Loan balances at such time that they are drawn.

The effective interest rate in effect as of December 31, 2023 was 15.9%. As of December 31, 2023, the carrying value of the Term Loan was $101,544, which is classified as a long-term liability on the consolidated balance sheets. The future principal payments due under the Oaktree Credit Agreement, excluding interest and the end of term charge, are as follows:

Year Ending December 31,	Principal
2024	$ —
2025	—
2026	24,750
2027	33,000
2028	33,000
Thereafter	19,250
Total	$ 110,000

During the year ended December 31, 2023, the Company recognized $2,468 and $10,708 of interest expense under the Hercules Credit Facility and Oaktree Credit Agreement, respectively, which is reflected in interest expense on the consolidated statement of operations and comprehensive loss. During the year ended December 31, 2022, the Company recognized $6,020 of interest expense related to the Hercules Credit Facility.

10. 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.

11. 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. On March 29, 2023, the Company's board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval, by increasing the number of authorized shares of the Company's Common Stock from 200,000,000 shares to 240,000,000 shares (the "Share Increase Amendment"). At the Company's annual meeting of stockholders held on June 22, 2023, the Company's stockholders approved the Share Increase Amendment. On June 27, 2023, the Company amended its Restated Certificate of Incorporation to reflect the Share Increase Amendment.

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, 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, 2023, the Company sold 7,711,199 shares of common stock under the 2021 Sales Agreement, at an average price of approximately $2.46 per share, raising aggregate net proceeds of approximately $18,159 after deducting an aggregate commission of approximately 3% and other issuance costs. During the year ended December 31, 2022, the Company sold 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.

Between December 31, 2023 and February 29, 2024, the Company sold 15,366,630 shares of common stock under the 2021 Sales Agreement, at an average price of approximately $1.23 per share, raising aggregate net proceeds of approximately $18,484 after deducting an aggregate commission of approximately 3% and other issuance costs.

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, 2023, 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, 2023, there were 2,545,586 shares available for future grant under the 2015 Plan.

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, 2023, there were 602,692 shares issued and 2,266,512 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. Purchase rights issued under the ESPP are intended to be qualified under Section 423 of the Internal Revenue Code ("IRC"). 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.

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

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, 2023, there were 2,382,884 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, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	14,940,034	$ 10.03	7.25	$ 11,608
Granted	2,508,553	5.44		
Exercised	(260,640)	3.36		
Forfeited	(2,343,835)	8.30		
Outstanding as of December 31, 2023	14,844,112	$ 9.64	5.71	$ —
Vested or expected to vest as of December 31, 2023	14,844,112	$ 9.64	5.66	$ —
Options exercisable as of December 31, 2023	10,488,694	$ 10.09	4.61	$ —

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2023, 2022, and 2021 was $4.51, $5.53, and $15.33 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2023, 2022, and 2021 was $438, $981, and $4,727, respectively.

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 562,000 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. In April 2023, the performance target associated with 50% of the performance-based stock options was achieved. Accordingly, the Company recorded $2,051 of compensation expense during the year ended December 31, 2023, with respect to these performance-based stock options, which represents a cumulative catch-up from the grant date through the achievement of the performance targets, and vesting of the remaining 50% of the options beginning in April 2023, partially offset by the reversal of stock-based compensation expense associated with the forfeiture of unvested awards. The remaining compensation expense associated with these performance-based stock options will be recognized ratably through April 2024, for all such options for which ongoing performance targets are achieved and service requirements are met.

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions ("RSUs") and restricted stock units with performance-based vesting conditions ("PSUs"). RSUs and PSUs represent the right to receive shares of common stock upon meeting

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

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 and PSU activity for the year ended December 31, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2022	1,549,540	$ 9.37
Granted	4,424,479	$ 4.14
Forfeited	(1,071,571)	$ 6.94
Vested	(1,524,644)	$ 7.22
Unvested restricted stock units as of December 31, 2023	3,377,804	$ 4.26

During the years ended December 31, 2023, 2022, and 2021, the Company granted 3,101,764, 1,302,844 and 643,998 RSUs, respectively. During the year ended December 31, 2023, 2022, and 2021, the Company granted 1,322,715, 0, and 125,000 PSUs, 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. PSUs vest according to the performance requirements of the awards, generally when the Company has determined that the specified performance targets have been achieved.

The aggregate intrinsic value of RSUs, including PSUs for which the performance conditions have been met, that vested during the years ended December 31, 2023, 2022 and 2021 was $4,729, $1,809, and $16, respectively.

In November 2023, as part of the corporate restructuring described in Note 13, *Restructuring*, the Company issued retention awards to employees of the Company in the form of RSUs which vest in two tranches on August 15, 2024, and May 15, 2025, subject to remaining actively employed with the Company through such date. The $1,255 in compensation expense associated with these awards will be recognized ratably over the vesting period. For the year ended December 31, 2023, the Company recognized $92 in compensation expense with respect to the retention awards.

In connection with the Restructuring Plan, the Company elected to accelerate the vesting of certain RSUs and PSUs previously granted to employees who were terminated as part of the Restructuring Plan. The Company accounted for the acceleration as a modification under applicable accounting standards, in which awards that were previously deemed not probable of vesting due to the employees' terminations became probable. Accordingly, the Company reversed $1,191 of compensation cost that had previously been recognized during the year ended December 31, 2023 on these awards and recorded the incremental fair value of the awards on the modification date of $261.

During the year ended December 31, 2021, the Company granted PSUs to two employees covering 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 PSUs 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. In April 2023, the remaining PSUs underlying these awards vested because the associated targets were achieved. Accordingly, the Company recorded the remaining $815 in compensation expense during the year ended December 31, 2023, with respect to these PSUs.

During the year ended December 31, 2023, the Company granted PSUs to employees covering an aggregate of 1,322,715 shares of common stock with a grant date fair value of $5.50. These PSUs begin to vest ratably only upon achievement of specified performance targets, which were achieved in April 2023. Accordingly, the Company recorded $4,293 in compensation expense during the year ended December 31, 2023, with respect to these PSUs. The remaining $1,092 in compensation expense associated with these PSUs will be recognized ratably through October 2024.

(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,		
	2023	2022	2021
Risk-free interest rate	3.64%	1.67%	0.73%
Expected term (in years)	6.0	6.0	5.4
Expected volatility	107.2%	104.0%	106.5%
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,		
	2023	2022	2021
Risk-free interest rate	5.01%	2.11%	0.97%
Expected term (in years)	0.5	0.5	0.5
Expected volatility	79.1%	99.0%	123.8%
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,		
	2023	2022	2021
Research and development expenses	$ 19,341	$ 13,429	$ 10,146
General and administrative expenses	14,760	12,053	10,076
	$ 34,101	$ 25,482	$ 20,222

As of December 31, 2023, the Company had an aggregate of $35,036 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.1 years.

12. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31,		
	2023	2022	2021
Numerator:			
Net loss attributable to common stockholders	$ (113,724)	$ (250,157)	$ (65,578)
Denominator:			
Weighted average common shares outstanding, basic and diluted	128,003,294	108,077,043	91,702,866
Net loss per share attributable to common stockholders, basic and diluted	$ (0.89)	$ (2.31)	$ (0.72)
Anti-dilutive potential common stock equivalents excluded from the calculation of net loss per share:			
Stock options to purchase common stock	14,844,112	14,940,034	11,517,189
Unvested restricted stock units	3,377,804	1,549,540	734,755
Shares issuable under employee stock purchase plan	297,784	89,593	165,047
Warrants to purchase common stock	1,177,433	—	—

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. Additionally, for the year ended December 31, 2023, the warrants to purchase common stock were excluded because the exercise price of the Tranche A Warrants is greater than the average fair value of the Company's common shares, and the necessary conditions for exercise of the Tranche B and Tranche C Warrants had not been met.

13. Restructuring

On November 2, 2023, the Company announced the Restructuring Plan to prioritize the commercialization of VOWST and the completion of the SER-155 Phase 1b study, while significantly reducing costs and supporting longer-term business sustainability. The Restructuring Plan included (i) a reduction of the Company's workforce by approximately 41% across the organization, resulting in the elimination of approximately 160 positions; (ii) significantly scaling back all non-partnered research and development activities other than the completion of the SER-155 Phase 1b study; and (iii) reducing general and administrative expenses, including consolidating office space.

During the year ended December 31, 2023, the Company recognized a restructuring charge of $5,606, which was incurred entirely in the fourth quarter of 2023, and which represents all restructuring charges expected to be incurred. Restructuring charges included approximately $5,345 of employee related termination costs in the form of salary continuation and cash severance payments, and $261 related to the acceleration of vesting of certain previously granted RSUs and PSUs. The following tables summarize the restructuring related charges and classification by line item within the Company's consolidated statements of operations during the year ended December 31, 2023:

	Year Ended December 31, 2023		
	Research and development	General and administrative	Total
Severance and other employee costs	3,318	2,027	5,345
Acceleration of unvested equity awards	163	98	261
Total restructuring charges	3,481	2,125	5,606

The restructuring charge is included in accrued expenses and other current liabilities in the Company's consolidated balance sheets. The following table presents changes in the restructuring liability for the year ended December 31, 2023 (in thousands):

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

	As of December 31, 2023
Restructuring expenses	$ 5,606
Less: stock-based compensation	$ (261)
Cash payments made	(265)
Remaining liability included in accrued expenses and other current liabilities	$ 5,080

The Company expects that substantially all of the accrued restructuring charges as of December 31, 2023 will be paid in cash by March 31, 2024.

Retention Awards

In November 2023, upon recommendation of the Company's Compensation Committee, the Board of Directors approved retention awards for employees of the Company in the form of RSUs which vest in two tranches on August 15, 2024, and May 15, 2025, subject to remaining actively employed with the Company through such date. The $1,255 in compensation expense associated with these awards will be recognized ratably over the vesting period.

14. Revenue from Contracts with Customers

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") (the "2021 License Agreement"). Under the terms of the 2021 License 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 VOWST, previously 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) VOWST 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 the first 2021 Collaboration Product, which is VOWST, in the 2021 Field in the United States until first regulatory approval, which was obtained on April 26, 2023.

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 is responsible for the manufacturing and supply for commercialization under a supply agreement that has been executed between the parties. Both parties performed pre-launch activities of VOWST prior to the first commercial sale in the United States, which occurred in June 2023. The Company was responsible for funding the pre-launch activities until first commercial sale of VOWST in the 2021 Licensed Territory and in accordance with a pre-launch plan, up to a specified cap. The Company is entitled to share equally in the commercial profits and losses of VOWST.

In connection with the 2021 License Agreement, the Company received an upfront payment of $175,000, and the Company received an additional $125,000 milestone payment in May 2023 after FDA approval of VOWST. The Company is eligible to receive additional payments of up to $235,000 if certain regulatory and sales milestones are achieved. The potential future milestone payments include up to $10,000 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 with twelve months’ prior written notice, effective only on or after the third anniversary of first commercial sale of VOWST in the 2021 Licensed Territory. 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)* (see Note 15, *Collaboration Profit and Loss*), 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 VOWST 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 VOWST 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 VOWST and the services to obtain regulatory approval of VOWST 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 VOWST 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 VOWST were not complex or specialized, could be performed by another qualified third party, were not expected to significantly modify or customize the license given that VOWST was late-stage intellectual property that completed clinical development and the services were 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 up-front payment of $175,000 compensated the Company for: (i) the co-exclusive license for VOWST 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 VOWST in the United States and (iii) pre-launch activities performed by Nestlé and the Company until the first commercial sale of VOWST 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 VOWST 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 (see Note 15, *Collaboration Profit and Loss*).

The Topic 606 transaction price of $139,500 was allocated to the co-exclusive license for VOWST and the services performed in accordance with the development and regulatory activity plan to obtain regulatory approval of VOWST 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 was recognized over time as the Company performed the services, which it completed in April 2023. During the years ended December 31, 2023, 2022, and 2021, the Company recognized $1,975, $4,114, and $2,068 of collaboration revenue - related party, respectively, related to the services performance obligation under the 2021 License Agreement.

The Company determined that any variable consideration related to the remaining 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 Company recognized the $125,000 regulatory milestone payment received in May 2023, which was fully allocated to the license performance obligation, as revenue in the consolidated statements of operations and comprehensive loss during the year ended December 31, 2023.

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 or commercialized, as applicable, for the treatment of CDI and IBD, including VOWST, 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 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

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

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 will be 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 VOWST, then 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, 2023, 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, 2023, 2022, and 2021 using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized ($650), $3,014, and $10,446 of collaboration revenue – related party, respectively, relating to the 2016 License Agreement.

As of December 31, 2023 and 2022, there was $95,364, and $96,689 of deferred revenue related to the unsatisfied portion of the performance obligation under the Nestlé agreements. As of December 31, 2023, 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.

Contract Balances from Contracts with Customers

The following tables present changes in the Company's contract liabilities during the year ended December 31, 2023 and 2022:

	Balance as of December 31, 2022	Additions	Deductions	Balance as of December 31, 2023
Year ended December 31, 2023				
Contract liabilities:				
Deferred revenue - related party	$ 96,689	1,644	(2,969)	$ 95,364

	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

During the year ended December 31, 2023, the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods (in thousands):

	Year Ended December 31,	
	2023	2022
Revenue recognized in the period from:		
Amounts included in the contract liability at the beginning of the period	$ 1,325	$ 7,128

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.

15. Collaboration Profit and Loss

License Agreement with NHSc Rx License GmbH (Nestlé)

Accounting Analysis

The 2021 License Agreement represents a separate contract between Nestlé and the Company. The 2021 License Agreement is within the scope of Topic 808, and has elements that are within the scope of Topic 606 (see Note 14, *Revenue from Contracts with Customers*) and Topic 808.

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 performance obligations under Topic 606. The Company and Nestlé were both active participants in the pre-launch activities and commercialization activities and were exposed to significant risks and rewards that were dependent on the commercial success of the activities in the arrangement. The amount allocated to the Topic 808 unit of accounting relates to the pre-launch activities performed prior to the first commercial sale of VOWST 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 sheets at the inception of the arrangement. On a quarterly basis, the Company and Nestlé provided financial information about the pre-launch activities performed by both parties. The Company reduced the $35,500 liability as the pre-launch activities were performed and it made payments to Nestlé for the pre-launch costs Nestlé incurred. As of December 31, 2023 and 2022, there was $10,064 and $34,770, respectively, included in accrued expenses and other current liabilities which represents costs incurred by Nestlé for pre-launch activities that have not yet been reimbursed by Seres.

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, 2023, 2022, and 2021, the Company recognized $1,446, $6,102, and $2,168 in research and development expenses and $4,242, $8,953, and $3,383 in general and administrative expenses, respectively, associated with pre-launch activities performed. The pre-launch activities were completed prior to the first commercial sale of VOWST, which occurred in June 2023.

Under the 2021 License Agreement with Nestlé, beginning with the first commercial sale of VOWST, which occurred in June 2023, net sales of VOWST are recorded by Nestlé and include gross sales net of discounts, rebates, allowances, and other applicable deductions. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. The Company records its share of the profits or losses from the sales of VOWST, including commercial and medical affairs expenses incurred by the Company, on a net basis, as collaboration (profit) loss sharing - related party. This treatment is in accordance with the Company's revenue recognition and collaboration policy, given that Nestlé and the Company are both active participants in commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities in the 2021 License Agreement. Nestlé provides the Company with reporting related to net sales of VOWST in accordance with U.S. generally accepted accounting principles in order to calculate and record collaboration profit or loss.

The collaboration (profit) loss sharing - related party line item also includes the Company's profit on the transfer of VOWST inventory to Nestlé, which represents the excess of the supply price paid by Nestlé over the Company's cost to manufacture VOWST, subject to a supply price cap applicable to product manufactured prior to commercial launch.

The collaboration (profit) loss sharing - related party line item also includes the collaboration loss related to pre-launch activities, which were completed prior to the first commercial sale of VOWST.

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

The components of the collaboration profit (loss) sharing for the years ended December 31, 2023, 2022, and 2021 are as follows:

	For the Year Ended December 31,		
	2023	2022	2021
Share of VOWST net loss	$ 18,873	$ —	$ —
Profit on transfer of VOWST inventory to Nestlé	(23,327)	—	—
Collaboration (profit)/loss related to pre-launch activities	5,158	1,004	(1,732)
Total collaboration (profit) loss sharing - related party	$ 704	$ 1,004	$ (1,732)

16. Commitments and Contingencies

Leases

Refer to Note 8 “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, 2023 or 2022.

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, 2023 and 2022.

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 substantially complete; and (ii) provide manufacturing services to the Company for its then SER-109 product candidate (now VOWST) and other products, as agreed to by the parties.

Under the terms of the Bacthera Agreement, the Company agreed to pay Bacthera a total of at least 256,000 CHF (or approximately $301,000) 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

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

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, 2023, 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, 2023, the Company has paid Bacthera $12,276 related to the construction of the dedicated manufacturing suite. As of December 31, 2023, the Company recorded $38,877 in other non-current assets in the accompanying consolidated balance sheet, including $30,049 related to the achievement of the substantial completion milestone that occurred in late 2023. These amounts will be recorded as part of the right-of-use asset upon lease commencement.

17. Income Taxes

During the years ended December 31, 2023, 2022 and 2021, 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,		
	2023	2022	2021
Federal statutory income tax rate	(21.0)%	(21.0)%	(21.0)%
Research and development tax credits	(4.3)	(3.1)	(16.6)
State taxes, net of federal benefit	(7.8)	(4.3)	(2.8)
Stock-based compensation	1.4	0.6	(0.4)
Uncertain tax position reserves	0.8	4.6	—
Other	(0.3)	0.3	0.4
Change in deferred tax asset valuation allowance	31.2	22.9	40.4
Effective income tax rate	—%	—%	—%

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

Net deferred tax assets as of December 31, 2023 and 2022 consisted of the following:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 142,506	$ 132,560
Research and development tax credit carryforwards	52,843	48,854
Section 174 capitalized research and development expenses	55,572	38,894
Stock-based compensation expense	25,898	20,048
Lease liability	29,855	29,717
Deferred revenue	27,452	29,922
Accrued expenses	3,540	4,044
Section 163(j) limitation	3,741	2,303
Depreciation and amortization	398	396
Other	169	200
Total deferred tax assets	$ 341,974	$ 306,938
Deferred tax liabilities:		
Depreciation and amortization	—	—
Right of use assets	(29,165)	(29,568)
Total deferred tax liabilities	(29,165)	(29,568)
Valuation allowance	$ (312,809)	$ (277,370)
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 $102,558 and $160,586 for the years ended December 31, 2023 and 2022, respectively. 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, 2023, the Company had net operating loss carryforwards (“NOLs”) for federal and state income tax purposes of $527,065 and $504,215, respectively. Federal NOLs of $119,800, generated before 2018, will begin expiring in varying amounts in 2035 unless utilized. The remaining federal NOLs of $407,265, 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, 2023, the Company also had available gross research and development tax credit carryforwards for federal and state income tax purposes of $53,928 and $11,455, respectively, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of $25,873.

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 IRC 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, 2023 and 2022. 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, 2023, 2022 and 2021 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,		
	2023	2022	2021
Valuation allowance at beginning of year	$ (277,370)	$ (220,114)	$ (193,736)
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	(35,439)	(57,256)	(26,378)
Valuation allowance as of end of year	$ (312,809)	$ (277,370)	$ (220,114)

During the year ended December 31, 2023, the Internal Revenue Service ("IRS") concluded their examination of the Company for the period ended December 31, 2018 related to the Company's 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, 2023 to account for the conclusions drawn by the IRS. 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, 2023, 2022, and 2021 were as follows:

	Year Ended December 31,		
	2023	2022	2021
Balance at beginning of year	$ 12,528	$ —	$ —
Increase in unrecognized tax benefits as a result of tax positions taken during the year	1,001	12,528	—
Reduction to unrecognized tax benefits	—	—	—
Balance at end of year	$ 13,529	$ 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, 2023 and 2022, 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.

18. Related Party Transactions

As described in Notes 14 and 15, 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"). NHSc Rx License GmbH is an affiliate of one of the Company's significant stockholders, Société des Produits Nestlé S.A. During the years ended December 31, 2023, 2022, and 2021, the Company recognized $126,975, $4,114, and $133,411 of related party revenue, respectively, associated with the 2021 License Agreement. As of the years ended December 31, 2023 and 2022, there was $0 and $1,976 of deferred revenue related to the 2021 License Agreement, respectively, which is classified as current in the consolidated balance sheets. As of December 31, 2023 and 2022 there was $28,053 and $34,770 included in accrued expenses and other liabilities, which represents amounts due to Nestlé pursuant to the 2021 License Agreement. As of December 31, 2023 and 2022, there was $7,730 and $0 of deferred income - related party included on the accompanying consolidated balance sheets, which represents the inventory transferred to Nestlé that Nestlé has not yet sold through to customers or transferred as free goods. The Company recognizes deferred income - related party as collaboration profit upon Nestlé's sale or transfer of such inventory to third parties. During the years ended

December 31, 2023 and 2022, the Company paid Nestlé $37,387 and $0 for Nestlé's share of the collaboration expenses pursuant to the 2021 License Agreement. During the years ended December 31, 2023 and 2022, the Company received $31,243 and $0 in payments from Nestlé for the transfer of VOWST to Nestlé. As of December 31, 2023 and 2022, there is $8,674 and $0 due from Nestlé pursuant to the 2021 License Agreement.

As described in Note 14, *Revenue from Contracts with Customers*, in January 2016, the Company entered into the 2016 License Agreement with Nestec, Ltd, succeeded by Société des Produits Nestlé S.A. 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. is one of the Company's significant stockholders. During the years ended December 31, 2023, 2022, and 2021, the Company recognized ($650), $3,014 and $10,446, respectively, of related party revenue associated with the 2016 License Agreement. As of December 31, 2023 and 2022, there was $95,364 and $94,713, 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 did not make any payment to or receive any payment from Nestlé during the years ended December 31, 2023 and 2022 pursuant to the 2016 License Agreement. There was no amount due from Nestlé pursuant to the 2016 License Agreement as of December 31, 2023 and 2022.

As described in Note 11, 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 consolidated balance sheet as of December 31, 2022. In June 2023, the Company elected not to renew the option and accordingly at such time, expensed the $833 option payment.

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, $0, and $1,575 during the years ended December 31, 2023, 2022, and 2021.

19. 401(k) Savings Plan

The Company has a defined contribution savings plan under Section 401(k) of the IRC. 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, 2023, 2022, and 2021 the Company recorded expense of $2,003, $1,921, and $1,087, respectively, for 401(k) match contributions.

Exhibit 4.2

DESCRIPTION OF CAPITAL STOCK

The following description of the capital stock of Seres Therapeutics, Inc. (the "Company," "we," "us," and "our") and certain provisions of our Restated Certificate of Incorporation, as amended ("Certificate of Incorporation") and Amended and Restated Bylaws ("Bylaws") are summaries and are qualified in their entirety by reference to the applicable provisions of our Certificate of Incorporation and Bylaws, which have been publicly filed with the Securities and Exchange Commission. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the General Corporation Law of the State of Delaware for more information.

Our authorized capital stock consists of:

- 240,000,000 shares of common stock, par value $0.001 per share; and
- 10,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our Certificate of Incorporation and Bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our Certificate of Incorporation. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

Rights Upon Liquidation. In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Other Rights. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Dividend

Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock. We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends for the foreseeable future. We currently expect to retain all future earnings, if any, for use in the development, operation and expansion of our business. Any determination to pay cash dividends in the future will depend upon, among other things, our results of operations, plans for expansion, tax considerations, available net profits and reserves, limitations under law, financial condition, capital requirements and other factors that our board of directors considers to be relevant.

Preferred Stock

Under the terms of our Certificate of Incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

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

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

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

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

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

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

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

Elimination of Stockholder Action by Written Consent. Our Certificate of Incorporation eliminates the right of stockholders to act by written consent without a meeting.

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

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

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

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

Choice of Forum. Our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or Certificate of Incorporation or Bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. 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 will be deemed to have notice of and to have consented to these choice of forum provisions. It is possible that a court of law could find the choice of forum provisions contained in our Certificate of Incorporation or Bylaws to be inapplicable or unenforceable if challenged in a proceeding or otherwise.

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

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

Exhibit 10.6

101 CAMBRIDGEPARK DRIVE
CAMBRIDGE, MASSACHUSETTS

LEASE SUMMARY SHEET

Execution Date:	September 22, 2021
Tenant:	Seres Therapeutics, Inc., a Delaware corporation
Tenant's Mailing Address Prior to Occupancy:	Seres Therapeutics, Inc. 200 Sidney Street, 4th Floor Cambridge, Massachusetts 02139
Landlord:	HCP/King 101 CPD LLC, a Delaware limited liability company
Building:	101 Cambridgepark Drive, Cambridge, Massachusetts. The Building is currently under construction and shall consist of five (5) stories and contain approximately 161,040 rentable square feet. The land (the "**Land**") on which the Building is located is described on Exhibit 2A attached hereto and made a part hereof.
Campus:	All of the land described on Exhibit 2B (including the Land described above, which Land is a portion of the land described on Exhibit 2B) together with the Building described above, the buildings now known as and numbered 87 Cambridgepark Drive ("**Building 87**"), and any other building and/or improvements constructed thereon. The Campus includes a parking garage under the Building (the "**Garage**") which is used in common by the tenants of the Campus.
Premises:	***Phase I Premises***: The fourth (4th) floor; ***Phase II Premises***: A portion of the first (1st) floor, and the fifth (5th) floor. Areas on the first (1st) floor (8,951 rentable square feet, including the Storage Premises (as defined below)), the fourth (4th) floor (35,575 rentable square feet), the fifth (5th) floor (35,575 rentable square feet, including a vivarium), and the Penthouse floor (2,614 rentable square feet), containing approximately 82,714 rentable square feet in the aggregate. The Premises consist of: **Prime Premises**, which will be located on the first (1st), fourth (4th) and fifth (5th) floors.

Penthouse Equipment Premises, which will be located on the Penthouse floor. The Penthouse Equipment Premises are located in a common room (the "**Penthouse Equipment Room**") which contains equipment of other tenants.

Storage Premises, which will be located on the first (1st) floor. The Storage Premises will be a caged area located in a common room (the "**Storage Room**") which contains storage areas of other tenants.

The term "**Premises**" shall mean the Prime Premises, the Penthouse Equipment Premises and the Storage Premises. The Premises are shown on the Lease Plans attached hereto as Exhibit 1A, Exhibit 1B, and Exhibit 1C and made a part hereof (the "**Lease Plans**").

Landlord and Tenant stipulate and agree that the rentable square footage of the Building and the rentable square footage of the Premises are based on the BOMA International Standard Method for Measuring Floor Area in Office Buildings (ANSI/BOMA Z65.1-2017) as modified for laboratory uses and applied in the Boston market and shall not be remeasured.

Property: The Building, the Garage, the Land, and other improvements located on, and to be constructed on, the Land.

Parking Areas: The parking structures (including the Garage located underneath the Building) located on the Campus that Landlord provides for parking by all tenants of space on the Property.

Term Commencement Date:

Phase I Term Commencement Date: The earlier of (i) the date that Tenant first commences to use the Phase I Premises, or any portion thereof, for any Permitted Use, or (ii) the Substantial Completion, as hereinafter defined, of Landlord's Work, as hereinafter defined applicable to the Phase I Premises. The parties estimate that that the Phase I Term Commencement Date will occur on or about October 15, 2022 ("**Estimated Phase I Term Commencement Date**").

Phase II Term Commencement Date: The earlier of (i) the date that Tenant first commences to use the Phase II Premises, or any portion thereof, for any Permitted Use or (ii) the Substantial Completion, as hereinafter defined, of Landlord's Work, as hereinafter defined applicable to the Phase II Premises. The parties estimate that that the Phase II Term Commencement Date will occur on or about December 1, 2022 ("**Estimated Phase II Term Commencement Date**").

The "**Estimated Term Commencement Date**" shall mean, as applicable, the Estimated Phase I Term Commencement Date or the Estimated Phase II Term Commencement Date.

	The "**Term Commencement Date**" shall mean, as applicable, the Phase I Premises Term Commencement Date or the Phase II Premises Term Commencement Date.
Rent Commencement Date:	***Phase I***: The date that is three (3) months after the Phase I Term Commencement Date ("**Phase I Rent Commencement Date**"). ***Phase II***: The date that is three (3) months after the Phase II Term Commencement Date ("**Phase II Rent Commencement Date**").
Expiration Date:	Ten (10) years and three (3) months after the Phase II Term Commencement Date, except that if the Phase II Term Commencement Date does not occur on the first day of a calendar month, then the Expiration Date shall be the last day of the calendar month in which the date ten (10) years and three (3) months after the Phase II Term Commencement Date occurs.
Extension Term:	Subject to Section 1.2 below, one (1) extension term of seven (7) years.
Landlord's **Contribution:**	Up to $20,678,500.00, subject to Article 4 below and Exhibit 4 attached hereto.
Permitted Uses:	Subject to Legal Requirements, Tenant shall have the right to use the following portions of the Premises only for the following uses: **Prime Premises**: General office, research, development, warehouse and laboratory use, and other ancillary uses (including, but not limited to, the Approved Vivarium Use) related to the foregoing. "**Approved Vivarium Use**" shall mean small rodents, subject to Section 4.6 of this Lease; **Penthouse Equipment Premises**: Installation, operation and maintenance of Tenant's Penthouse Equipment; and **Storage Premises**: The storage of Tenant's Hazardous Materials, waste and other materials used or generated by Tenant in the Premises.

Base Rent:

RENT YEAR	ANNUAL BASE RENT	MONTHLY PAYMENT
Phase I Premises only:		
Months 1-3 of Rent Year 1	$0.00	$0.00
Months 4-12 of Rent Year 1	$3,706,599.00*	$308,883.25
Phase II Premises only:		
Phase II Term Commencement Date - the last day of the third (3rd) calendar month following the Phase II Term Commencement Date	$0.00	$0.00
The date which is four (4) months after the Phase II Term Commencement Date - end of Rent Year 1	$4,647,515.00*	$387,292.92
Entire Premises:		
Rent Year 2	$8,604,737.42	$717,061.45
Rent Year 3	$8,862,879.54	$738,573.30
Rent Year 4	$9,128,765.93	$760,730.49
Rent Year 5	$9,402,628.91	$783,552.41
Rent Year 6	$9,684,707.77	$807,058.98
Rent Year 7	$9,975,249.01	$831,270.75
Rent Year 8	$10,274,506.48	$856,208.87
Rent Year 9	$10,582,741.67	$881,895.14
Rent Year 10	$10,900,223.92	$908,351.99
Rent Year 11	$11,227,230.64	$935,602.55

*annualized

Rent Year:	Rent Year 1 shall be the twelve-(12)-month period commencing as of the Phase I Term Commencement Date, except that if the Phase I Term Commencement Date occurs on other than the first day of a calendar month, then Rent Year 1 shall commence as of the Phase I Term Commencement Date and shall end on the last day of the calendar month in which the first anniversary of the Phase I Term Commencement Date occurs. Each Rent Year after Rent Year 1 shall be the twelve-(12)-month period immediately following the preceding Rent Year.
Operating Costs and Taxes:	See Sections 5.2 and 5.3.
Tenant's Share:	A fraction, the numerator of which is the number of rentable square feet in the Premises and the denominator of which is the number of rentable square feet in the Building. As of the Execution Date, Tenant's Share with respect to the Premises is 51.36%.
Letter of Credit:	$6,265,585.53, subject to adjustment as set forth in Section 7.6 below.
Guarantor:	None.

EXHIBIT 1A	LEASE PLAN - PRIME PREMISES
EXHIBIT 1B	LEASE PLAN - STORAGE PREMISES
EXHIBIT 1C	LEASE PLAN - PENTHOUSE EQUIPMENT PREMISES
EXHIBIT 2A	LEGAL DESCRIPTION - LAND
EXHIBIT 2B	LEGAL DESCRIPTION
EXHIBIT 3	BASE BUILDING CAPACITIES
EXHIBIT 4	WORK LETTER
EXHIBIT 4-1	BASE BUILDING PLANS
EXHIBIT 4-2	TENANT/LANDLORD RESPONSIBILITY MATRIX
EXHIBIT 4-3	INITIAL FIT PLAN OF TENANT IMPROVEMENT WORK
EXHIBIT 5	FORM OF LETTER OF CREDIT
EXHIBIT 6	LANDLORD'S SERVICES
EXHIBIT 7	TENANT'S HAZARDOUS MATERIALS
EXHIBIT 7-1	TENANT'S CONTROL AREAS
EXHIBIT 8	RULES AND REGULATIONS
EXHIBIT 8-1	BUILDING RULES AND REGULATIONS
EXHIBIT 8-2	CONSTRUCTION RULES AND REGULATIONS
EXHIBIT 9	TENANT WORK INSURANCE SCHEDULE
EXHIBIT 10	LEED GUIDELINES
EXHIBIT 11	PARKING AND TRAFFIC DEMAND MANAGEMENT PLAN

TABLE OF CONTENTS

THIS INDENTURE OF LEASE (this "**Lease**") is hereby made and entered into on the Execution Date by and between Landlord and Tenant.

Each reference in this Lease to any of the terms and titles contained in any Exhibit attached to this Lease shall be deemed and construed to incorporate the data stated under that term or title in such Exhibit. All capitalized terms not otherwise defined herein shall have the meanings ascribed to them as set forth in the Lease Summary Sheet which is attached hereto and incorporated herein by reference.

CREATION OF CONDOMINIUM

(1) Tenant hereby acknowledges and agrees that, at Landlord's sole election, Landlord may establish a condominium (the "**Condominium**") by filing a Master Deed and Declaration of Trust of the Condominium. If Landlord makes such election, then the Building and the building known as 87 Cambridgepark Drive ("**87 Building**") shall each be Units of the Condominium, provided that no such Condominium shall materially adversely affect Tenant's rights or increase Tenant's obligations under this Lease (the Master Deed, as may be amended from time to time, being referred to herein as the "**Master Deed**", and the Declaration of Trust, as may be amended from time to time, being referred to herein as the "**Declaration of Trust**").

(2) The Lease shall be subject and subordinate, in all respects, to the Master Deed, the Declaration of Trust, and the other documents establishing the Condominium (the "**Condominium Documents**"). Tenant shall, at Landlord's request, execute a reasonable instrument, in recordable form, confirming that the Lease is subject and subordinate to the Condominium Documents.

1. LEASE GRANT; TERM; APPURTENANT RIGHTS; EXCLUSIONS

1.1 Lease Grant. The parties intend that Tenant lease and occupy the Premises as follows:

(a) Phase I Premises. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the Phase I Premises upon and subject to terms and conditions of this Lease, for a term of years commencing on the Phase I Premises Term Commencement Date and, unless earlier terminated or extended pursuant to the terms hereof, ending on the Expiration Date (the "**Initial Term**"; the Initial Term and any duly exercised Extension Term are hereinafter collectively referred to as the "**Term**"). From the Phase I Premises Term Commencement Date until the Phase II Premises Term Commencement Date, each reference contained in the Lease to the "Premises" shall be considered to be a reference to the Phase I Premises only, and each reference contained in this Lease to the "Term" shall apply to the Phase I Premises only.

(b) Phase II Premises. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the Phase II Premises upon and subject to terms and conditions of this Lease, for a term of years commencing on the Phase II Premises Term Commencement Date and, unless earlier terminated or extended pursuant to the terms hereof, ending on the Expiration Date. From and after the Phase II Premises Term Commencement Date, each reference contained in the Lease to the "Premises" shall be considered to be a reference to the Phase I Premises and the Phase II Premises, collectively, and each reference to the "Term" shall apply to the entire Premises.

1.2 Extension Term.

(a) Provided that the following conditions, which may be waived by Landlord in its sole discretion, are satisfied (i) Tenant, an Affiliated Entity (hereinafter defined) and/or a Successor (hereinafter defined) is/are then occupying seventy-five (75%) percent of the Premises; and (ii) no Event of Default nor an event which, with the passage of time and/or the giving of notice would constitute an Event of Default has occurred (1) as of the date of the Extension Notice (hereinafter defined), and (2) at the commencement of the Extension Term (hereinafter defined), Tenant shall have the option to extend the Term for one (1) additional term of seven (7) years (the "**Extension Term**"), commencing as of the expiration of the Initial Term. Tenant must exercise such option to extend, if at all, by giving Landlord written notice (the "**Extension Notice**") on or before the date that is twelve (12) months prior to the expiration of the Initial Term, but in no event earlier than fifteen (15) months prior to the expiration of the Initial Term, *time being of the essence*. Upon the timely giving of such notice, the Term shall be deemed extended upon all of the terms and conditions of this Lease, except that Base Rent during the Extension Term shall be calculated in accordance with this Section 1.2, Landlord shall have no obligation to construct or renovate the Premises. If Tenant fails to give timely notice, as aforesaid, Tenant shall have no further right to extend the Term. Notwithstanding the fact that Tenant's proper and timely exercise of such option to extend the Term shall be self-executing, the parties shall promptly execute a lease amendment reflecting such Extension Term after Tenant exercises such option. The execution of such lease amendment shall not be deemed to waive any of the conditions to Tenant's exercise of its rights under this Section 1.2.

(b) The Base Rent during the Extension Term (the "**Extension Term Base Rent**") shall be determined in accordance with the process described hereafter. Extension Term Base Rent shall be the fair market rental value of the Premises then demised to Tenant as of the commencement of the Extension Term as determined in accordance with the process described below, for renewals of first class office/research/laboratory building/campus in the Alewife area of Cambridge, Massachusetts real estate market (the "**Market Area**") of equivalent quality, size, utility and location, with the length of the Extension Term, the credit standing of Tenant and all other relevant factors to be taken into account. Within thirty (30) days after receipt of the Extension Notice, Landlord shall deliver to Tenant written notice of its determination of the Extension Term Base Rent for the Extension Term. Tenant shall, within thirty (30) days after receipt of such notice, notify Landlord in writing whether Tenant accepts or rejects Landlord's determination of the Extension Term Base Rent ("**Tenant's Response Notice**"). If Tenant fails timely to deliver Tenant's Response Notice, Landlord's determination of the Extension Term Base Rent shall be binding on Tenant.

(c) If and only if Tenant's Response Notice is timely delivered to Landlord and indicates both that Tenant rejects Landlord's determination of the Extension Term Base Rent and desires to submit the matter to arbitration, then the Extension Term Base Rent shall be determined in accordance with the procedure set forth in this Section 1.2(c). In such event, within ten (10) days after receipt by Landlord of Tenant's Response Notice indicating Tenant's desire to submit the determination of the Extension Term Base Rent to arbitration, Tenant and Landlord shall each notify the other, in writing, of their respective selections of an appraiser (respectively, "**Landlord's Appraiser**" and "**Tenant's Appraiser**"). Landlord's Appraiser and Tenant's Appraiser shall then jointly select a third appraiser (the "**Third Appraiser**") within ten (10) days of their appointment.

All of the appraisers selected shall be individuals with at least five (5) consecutive years' commercial appraisal experience for office and laboratory space in the area in which the Premises are located, shall be members of the Appraisal Institute (M.A.I.), and, in the case of the Third Appraiser, shall not have acted in any capacity for either Landlord or Tenant within five (5) years of his or her selection. The three appraisers shall determine the Extension Term Base Rent in accordance with the requirements and criteria set forth in Section 1.2(b) above, employing the method commonly known as Baseball Arbitration, whereby Landlord's Appraiser and Tenant's Appraiser each sets forth its determination of the Extension Term Base Rent as defined above, and the Third Appraiser must select one or the other (it being understood that the Third Appraiser shall be expressly prohibited from selecting a compromise figure). Landlord's Appraiser and Tenant's Appraiser shall deliver their determinations of the Extension Term Base Rent to the Third Appraiser within five (5) days of the appointment of the Third Appraiser and the Third Appraiser shall render his or her decision within ten (10) days after receipt of both of the other two determinations of the Extension Term Base Rent. The Third Appraiser's decision shall be binding on both Landlord and Tenant. Each party shall bear the cost of its own appraiser and the cost of the Third Appraiser shall be paid by the party whose determination is not selected.

1.3 Appurtenant Rights.

(a) Common Areas. Subject to the terms of this Lease and the Rules and Regulations (hereinafter defined), Tenant shall have, as appurtenant to the Premises, rights to use in common with others entitled thereto, the following areas (such areas are hereinafter referred to as the "**Common Areas**"): (i) the common loading docks, hallways, lobby, and elevator of the Building serving the Premises, (ii) the common lavatories located on the floor(s) on which the Premises are located, (iii) common walkways and driveways necessary for access to the Building, (iv) the Parking Areas, (v) the courtyard deck area, and (vi) other areas and facilities located in the Building, on the Land, or elsewhere on the Campus designated by Landlord from time to time for the common use of tenants of the Building and other entitled thereto; and no other appurtenant rights or easements. "Rules and Regulations" shall be defined as the rules and regulations promulgated by Landlord pursuant to, and subject to, the provisions of Section 18.1 of the Lease.

(b) Parking. During the Term, Landlord shall, subject to the terms hereof and Section 4.4 below, make available and Tenant shall lease one (1) parking space per 1,000 rentable square feet of the Premises (i.e., eighty-three (83) parking spaces based on 82,714 square feet) for Tenant's use in the Parking Areas serving the Building. The number of parking spaces in the Parking Areas reserved for Tenant, as modified pursuant to this Lease or as otherwise permitted by Landlord, are hereinafter referred to as the "**Parking Spaces**." The rate for Parking Spaces shall be the prevailing market rate established from time to time by Landlord or the Garage Operator, as the case may be. The current monthly rate for each Parking Space is One Hundred Seventy-Five and 00/100 Dollars ($175.00). Notwithstanding the foregoing, the initial rate for each Parking Space shall be established upon the Phase I Term Commencement Date. Tenant shall have no right to hypothecate or encumber the Parking Spaces, and shall not sublet, assign, or otherwise transfer the Parking Spaces other than to employees of Tenant occupying the Premises or to a Successor (hereinafter defined), an Affiliated Entity (hereinafter defined), or a transferee pursuant to an approved Transfer under Section 13 of this Lease. Subject to Landlord's right to reserve parking for other tenants of the Building, said Parking Spaces will be on an unassigned, non-reserved basis, and shall be subject to such Rules and Regulations, as may be in effect for the use of the parking

areas from time to time. If during the Term of this Lease, Landlord grants or designates reserved parking spaces in the Parking Areas serving the Building to any other tenant of the Building, then Tenant shall be entitled to receive a corresponding number of such reserved parking spaces for a monthly rental fee payable by Tenant as Additional Rent hereunder, at Landlord's prevailing rate for such reserved parking spaces. Reserved and handicap parking spaces must be honored. Landlord hereby reserves the right to enter into a management agreement or lease with an entity for the Garage ("**Garage Operator**"). In such event, Tenant, upon request of Landlord, shall enter into a parking agreement with the Garage Operator and pay the Garage Operator the monthly charge established hereunder, and Landlord shall have no liability for claims arising through acts or omissions of the Garage Operator unless caused by the negligence or willful misconduct of Landlord. It is understood and agreed that the identity of the Garage Operator may change from time to time during the Term. In connection therewith, any parking lease or agreement entered into between Tenant and a Garage Operator shall be freely assignable by such Garage Operator or any successors thereto. Landlord shall have the right, upon at least three (3) months' prior written notice to Tenant, to temporarily relocate all or any portion of the Parking Spaces in to other portions of the Property and/or parking areas owned, controlled or leased by Landlord and located in the vicinity of the area. If Landlord elects to relocate Tenant's Parking Spaces, Landlord (at its sole cost and expense) shall provide, for the duration of such relocation, shuttle service to and from such temporary parking location. In addition, Landlord may, at its election, implement valet or managed parking in order to accommodate the parking needs of the Property from time to time.

(c) Common Acid Neutralization Tank.

(i) Landlord shall, as part of Landlord's Work, install an acid neutralization tank (the "**Common Acid Neutralization Tank**") on the first (1st) floor of the Building (the "**PH System Room**") for Tenant's use, in common with other tenants in the Building, in accordance with the provisions of this Lease. Landlord shall obtain, and maintain, all governmental permits and approvals necessary for the operation and maintenance of the Common Acid Neutralization Tank in accordance with Legal Requirements. In addition, as part of Landlord's Work, Landlord may install a lab waste sampling port within the Premises to allow Landlord to take samples of Tenant's effluent from time to time and ensure compliance with Legal requirements, including the MWRA regulations.

(ii) Except as otherwise provided below, the cost of operating, maintaining, repairing and restoring the Common Acid Neutralization Tank shall be included in Operating Costs. Notwithstanding the foregoing, if Landlord reasonably determines that Tenant is using the Common Acid Neutralization Tank in excess of its proportionate share of the total volume thereof, Landlord may elect, at Tenant's expense, to furnish and install metering equipment to measure Tenant's usage of the Common Acid Neutralization Tank. In such event, Tenant shall, within thirty (30) days after Landlord's written demand therefor from time to time, pay to Landlord, as Additional Rent, the full amount of any charges (including, without limitation, any services charges) attributable to Tenant's usage as measured by such meter.

(iii)Tenant agrees to be responsible for any damage caused to the Building, Property or the Common Acid Neutralization Tank in connection with Tenant's use thereof. Except (subject to Section 14.5) with respect to Claims, to the extent caused by the negligence or willful misconduct of Landlord or any Landlord Parties, Tenant shall indemnify,

save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord) and hold the Landlord Parties, harmless from and against any and all Claims, including (A) damages for the loss of or restriction on use of rentable or usable space of the Building, and (B) sums paid in settlement of Claims that arise during or after the Term as a result of Tenant's improper use of the Common Acid Neutralization Tank. This indemnification by Tenant includes costs actually incurred by Landlord: (1) in connection with any investigation required by any Governmental Authority of site conditions, (2) in connection with any investigation required by Landlord pursuant to which it is determined that Tenant has improperly used the Common Acid Neutralization Tank, and (3) any clean-up, remediation, and/or removal of any Hazardous Materials and/or restoration of the Property required by any Governmental Authority caused by Tenant's improper use of the Common Acid Neutralization Tank.

(iv)Tenant shall have no right to (A) make any changes, alterations, additions, decorations or other improvements to the Common Acid Neutralization Tank or (B) otherwise access the PH System Room.

(d) Generator. Reference is made to the fact the Building is served by a 1250 kw emergency generator ("**Generator**"). Tenant shall be permitted to connect certain equipment the Generator, provided that the aggregate electrical demand of all equipment connected by Tenant to the Generator at any time shall not exceed Tenant's pro rata share (based upon relative rentable floor area) of the Generator. Landlord's sole obligation for either providing emergency generators or providing emergency back-up power to Tenant shall be: (i) to provide emergency generators with not less than the stated capacity of the emergency generators located in the Building as of the Term Commencement Date, and (ii) to contract with a third party to maintain the emergency generators as per the manufacturer's standard maintenance guidelines. Landlord shall have no obligation to provide Tenant with operational emergency generators or back-up power or to supervise, oversee or confirm that the third party maintaining the emergency generators is maintaining the generators as per the manufacturer's standard guidelines or otherwise. During any period of replacement, repair or maintenance of the emergency generators when the emergency generators are not operational, including any delays thereto due to the inability to obtain parts or replacement equipment, Landlord shall have no obligation to provide Tenant with an alternative back-up generator or generators or alternative sources of back-up power. Tenant expressly acknowledges and agrees that Landlord does not guaranty that such emergency generators will be operational at all times or that emergency power will be available to the Premises when needed. In no event shall Landlord be liable to Tenant or any other party for any damages of any type, whether actual or consequential, suffered by Tenant or any such other person in the event that any emergency generator or back-up power or any replacement thereof fails or does not provide sufficient power.

(e) Penthouse Equipment Premises. Tenant may, as part of Tenant's Work or in accordance with the terms and conditions of Article 11 below, install certain equipment within a portion of the Penthouse of the Building designated by Landlord (the "**Penthouse Equipment Premises**"), as shown on Exhibit 1C (any equipment installed within the Penthouse Equipment Premises, as the same may be modified, altered or replaced during the Term, is collectively referred to herein as "Tenant's Penthouse Equipment"), for Tenant's exclusive use during the Term in accordance with the provisions of this Lease, including, without limitation, Section 11 hereof. Tenant shall have the right, throughout the Term of the Lease, as the same may be extended, to

use Tenant's Penthouse Equipment in accordance with Legal Requirements. Tenant shall not operate Tenant's Penthouse Equipment until Landlord has obtained copies of all required governmental permits, licenses, and authorizations necessary for the installation and operation thereof. In addition, following the delivery of Tenant's Penthouse Equipment by Landlord in good working order and repair, Tenant shall comply with all reasonable construction rules and regulations promulgated by Landlord in connection with the installation, maintenance and operation of Tenant's Penthouse Equipment. Landlord shall have no obligation to provide any services including, without limitation, electric current or gas service, to the Penthouse Equipment Premises or to Tenant's Penthouse Equipment, provided, however, Landlord, as part of the Tenant Improvement Work, will install the initial necessary utility connections between Tenant's Penthouse Equipment and the Premises (which utility connections shall be deemed part of Tenant's Penthouse Equipment). Tenant shall be responsible for the cost of repairing and maintaining Tenant's Penthouse Equipment and the cost of repairing any damage to the Building, or the cost of any necessary improvements to the Building, caused by or as a result of the installation, replacement and/or removal of Tenant's Penthouse Equipment. Except for Landlord's Warranty, as set forth in Section 15 of Exhibit 4, Landlord makes no warranties or representations to Tenant as to the suitability of the Penthouse Equipment Premises for the installation and operation of Tenant's Penthouse Equipment. In the event that at any time during the Term, Landlord determines, in its sole but bona fide business judgment, that the operation and/or periodic testing of Tenant's Penthouse Equipment interferes with the operation of the Building or the business operations of any of the occupants of the Building, then Tenant shall, upon notice from Landlord, cause all further testing of Tenant's Penthouse Equipment to occur after normal business hours (hereinafter defined).

1.4Tenant's Access. Commencing on the Phase I Premises Term Commencement Date as to the Phase I Premises and commencing on the Phase II Premises Term Commencement Date as to the Phase II Premises, Tenant shall have access to the Phase I Premises and the Phase II Premises, as applicable, twenty-four (24) hours a day, seven (7) days a week, except in an emergency, and subject to Landlord's reasonable Building security requirements, causes beyond Landlord's reasonable control, Legal Requirements, the Rules and Regulations, the terms of this Lease, Force Majeure (hereinafter defined) and matters of record. Tenant and its employees shall have access to the Building after normal business hours by means of a card reader access system.

1.5No recording // Notice of Lease. Neither party shall record this Lease. Tenant shall not record a memorandum of this Lease and/or a notice of this Lease. Notwithstanding the foregoing, if the Initial Term plus any Extension Term(s) exceed in the aggregate seven (7) years, Landlord agrees to join in the execution, in recordable form, of a statutory notice of lease and/or written declaration in which shall be stated the Term Commencement Date, the Rent Commencement Date, the number and length of the Extension Term(s) and the Expiration Date, which notice of lease may be recorded by Tenant with the Middlesex South Registry of Deeds and/or filed with the Middlesex South Registry District of the Land Court, as appropriate (alternatively and collectively, the "**Registry**") at Tenant's sole cost and expense. If a notice of lease was previously recorded with the Registry, upon the expiration or earlier termination of this Lease, Landlord shall deliver to Tenant a notice of termination of Lease and Tenant shall promptly execute, acknowledge, and deliver the same (together with any other instrument(s) that may be necessary in order to record and/or file same with the Registry) to Landlord for Landlord's

execution and recordation with the Registry, which obligation shall survive the expiration or earlier termination of the Lease.

1.6Exclusions. The following are expressly excluded from the Premises and reserved to Landlord: all the perimeter walls of the Premises (except the inner surfaces thereof), the Common Areas, and any space in or adjacent to the Premises used for shafts, stacks, pipes, conduits, wires and appurtenant fixtures, fan rooms, ducts, electric or other utilities, sinks or other Building facilities, and the use of all of the foregoing, except as expressly permitted pursuant to Section 1.3(a) above.

2. RIGHTS RESERVED TO LANDLORD

2.1Additions and Alterations. Landlord reserves the right, at any time and from time to time, to make such changes, alterations, additions, improvements, repairs or replacements in or to the Property (including the Premises but, with respect to the Premises, only for purposes of repairs, maintenance, replacements and the exercise of any other rights expressly reserved to Landlord herein) and the fixtures and equipment therein, as well as in or to the street entrances and/or the Common Areas, as it may deem necessary or desirable, provided, however, that there be no material obstruction of permanent access to, or material interference with the use and enjoyment of, the Premises by Tenant. Subject to the foregoing, Landlord expressly reserves the right to temporarily close all, or any portion, of the Common Areas for the purpose of making repairs or changes thereto.

2.2 Additions to the Property.

(a) Landlord may at any time or from time to time (i) construct additional building(s) and improvements and related site improvements (collectively, "**Future Development**") in all or any part of the Property and/or (ii) change the location or arrangement of any improvement outside the Building in or on the Property or all or any part of the Common Areas, or add or deduct any land to or from the Property; provided that there shall be no material increase in Tenant's obligations or material interference with Tenant's rights under this Lease in connection with the exercise of the foregoing reserved rights.

(b) In case any excavation shall be made for building or improvements or for any other purpose upon the land adjacent to or near the Premises, Tenant will afford without charge to Landlord, or the person or persons, firms or corporations causing or making such excavation, license to enter upon the Premises for the purpose of doing such work as Landlord or such person or persons, firms or corporation shall deem to be necessary to preserve the walls or structures of the Building from injury, and to protect the Building by proper securing of foundations.

(c) Landlord and Tenant each hereby acknowledges and agrees that, in connection with any Future Development, (i) Landlord shall have the right to enter into, and subject the Property to the terms and conditions of, a commercially reasonable reciprocal easement agreement with any one or more of the neighboring property owners in order to create a commercial campus-like setting ("**REA**"); (ii) upon Landlord's request in connection with the recording of the REA, Tenant shall execute a commercially reasonable instrument in recordable form making this Lease subject and subordinate to the REA; (iii) Landlord shall have the right to

subdivide the Property so long as Tenant continues to have all of the rights and obligations contained in this Lease (e.g., the appurtenant right to use all Common Areas); and (iv) Tenant shall execute such reasonable documents (which may be in recordable form) evidencing the foregoing with reasonable promptness upon Landlord's request.

2.3Name and Address of Building. Landlord reserves the right at any time and from time to time to change the name or address of the Building and/or the Property, provided Landlord gives Tenant at least three (3) months' prior written notice thereof.

2.4Landlord's Access. Subject to the terms hereof, Tenant shall (a) upon reasonable advance notice, which may be oral (except that no notice shall be required in emergency situations), permit Landlord and any holder of a Mortgage (hereinafter defined) (each such holder, a "**Mortgagee**"), and the agents, representatives, employees and contractors of each of them, to have reasonable access to the Premises at all reasonable hours for the purposes of inspection, making repairs, replacements or improvements in or to the Premises or the Building or equipment therein (including, without limitation, sanitary, electrical, heating, air conditioning or other systems), complying with all applicable laws, ordinances, rules, regulations, statutes, by-laws, court decisions and orders and requirements of all public authorities (collectively, "**Legal Requirements**"), or exercising any right reserved to Landlord under this Lease (including without limitation the right to take upon or through, or to keep and store within the Premises all necessary materials, tools and equipment); (b) permit Landlord and its agents and employees, at reasonable times, upon reasonable advance notice, to show the Premises during normal business hours (i.e. Monday - Friday 7 A.M. - 6 P.M., Saturday 7 A.M. - 12 P.M., excluding holidays) to any prospective Mortgagee or purchaser of the Building and/or the Property or of the interest of Landlord therein, and, during the last twelve (12) months of the Term or at any time after the occurrence of an Event of Default, prospective tenants; and (c) upon reasonable prior written notice from Landlord, permit Landlord and its agents, at Landlord's sole cost and expense, to perform environmental audits, environmental site investigations and environmental site assessments ("**Site Assessments**") in, on, under and at the Premises and the Land, it being understood that Landlord shall repair any damage arising as a result of the Site Assessments, and such Site Assessments may include both above and below the ground testing and such other tests as may be necessary or appropriate to conduct the Site Assessments. In addition, to the extent that it is necessary to enter the Premises in order to access any area that serves any portion of the Building outside the Premises, then Tenant shall, upon as much advance notice as is practical under the circumstances, and in any event at least twenty-four (24) hours' prior written notice (except that no notice shall be required in emergency situations), permit contractors engaged by other occupants of the Building to pass through the Premises in order to access such areas but only if accompanied by a representative of Landlord. The parties agree and acknowledge that, despite reasonable and customary precautions (which Landlord agrees it shall exercise), any property or equipment in the Premises of a delicate, fragile or vulnerable nature may nevertheless be damaged in the course of performing Landlord's obligations. Accordingly, Tenant shall take reasonable protective precautions with unusually fragile, vulnerable or sensitive property and equipment.

2.5Pipes, Ducts and Conduits. Subject to the provisions of Section 2.4 and other provisions of this Lease, Tenant shall permit Landlord to erect, use, maintain and relocate pipes, ducts and conduits in and through the Premises, provided the same do not reduce the rentable square footage of the Premises, other than by a de minimis amount, or adversely affect the appearance of the Premises.

2.6Minimize Interference. Except in the event of an emergency, Landlord shall use commercially reasonable efforts to minimize any interference with Tenant's business operations and use and occupancy of the Premises in connection with the exercise any of the foregoing rights under this Section 2.

3. CONDITION OF PREMISES; CONSTRUCTION.

3.1Condition of Premises. Tenant acknowledges and agrees that Tenant is leasing the Premises in their "**AS IS**," "**WHERE IS**" condition and with all faults on the Execution Date, without representations or warranties, express or implied, in fact or by law, of any kind, and without recourse to Landlord, except that Landlord shall perform Landlord's Work in accordance with the provisions of this Section 3 and Exhibit 4. Tenant shall not exceed its allotted base building capacities defined on Exhibit 3 attached hereto.

3.2 Landlord's Work.

(a) Subject to Force Majeure and any Tenant Delay, as hereinafter defined, Landlord shall perform Landlord's Work in order to prepare the Premises for Tenant's use and occupancy in accordance with Exhibit 4 attached hereto. Landlord shall use diligent efforts to achieve Substantial Completion of the applicable portion of Landlord's Work by the applicable Estimated Term Commencement Date. However, except to the extent that such failure constitutes a delay in the occurrence of the Term Commencement Date (as provided in the definition of the Term Commencement Date), and: (i) Tenant's sole remedies shall be a delay in the Term Commencement Date, (ii) Tenant shall have no claim or rights against Landlord, and Landlord shall have no liability or obligation to Tenant in the event of delay in Landlord's Work, and (iii) no delay in Landlord's Work shall have any effect on the parties rights or obligations under this Lease.

(b) Definitions.

(i) "**Tenant Delay**" shall mean any act or omission by Tenant and/or Tenant's agents, employees or contractors (collectively with Tenant, the "**Tenant Parties**") which causes a delay in the commencement or performance of Landlord's Work or the issuance of a certificate of occupancy for the Premises. Notwithstanding the foregoing, except where a Tenant Delay arises from Tenant's failure timely to act within on or before a date or time period expressly set forth in the Lease (in which event no Tenant Delay Notice shall be required): (x) in no event shall any act or omission be deemed to be a Tenant Delay until and unless Landlord has given Tenant written notice (the "**Tenant Delay Notice**") advising Tenant (a) that a Tenant Delay is occurring, and (b) of the basis on which Landlord has determined that a Tenant Delay is occurring, and (y) no period of time prior to the time that Tenant receives a Tenant Delay Notice shall be included in the period of time charged to Tenant pursuant to such Tenant Delay Notice.

(ii) "**Substantially Complete**" or "**Substantial Completion**," when referring to Landlord's Work shall mean that: (1) Landlord's Work is completed, other than minor work which does not materially affect Tenant's use of, or access to, the Premises, (2) the Premises and those portions of the Common Areas of the Building which affect Tenant's occupancy are in conformance with all applicable building codes, permits, laws and regulations, including without limitation, ADA, (3) all structural elements and subsystems of the Building, including but not limited to HVAC, mechanical, electrical, lighting, plumbing, and life safety systems, will be in good working condition and repair, (4) Landlord has delivered to Tenant (x) a certificate of substantial completion from Landlord's architect stating that Landlord's Work is substantially complete, and (y) a certificate of occupancy (which may be a temporary certificate of occupancy) relating to the Premises or an equivalent approval provided by the City of Cambridge to evidence Tenant's right to lawfully occupy the Premises, except to the extent that such certificate of occupancy or such approval from the City of Cambridge cannot be obtained by reason of the failure of Tenant to perform Tenant's Work (as defined in Exhibit 4) or to install or make operational its modular furniture or telecommunications equipment, and (5) such evidence as is customarily provided by the City of Cambridge to evidence its acceptance of Landlord's Work and Tenant's right to lawfully occupy the Premises (e.g., sign-offs on the Building permit by all applicable City of Cambridge departments or a certificate of occupancy, which may be a temporary certificate of occupancy) has been provided by the City of Cambridge. No costs incurred by Landlord in satisfying the definition of Substantial Completion shall be included in Operating Costs. Notwithstanding anything to the contrary herein contained, in the event that Landlord's Work is delayed by reason of any Tenant Delay, then Landlord shall be deemed to have achieved Substantial Completion of Landlord's Work on the date that Landlord would have achieved Substantial Completion of Landlord's Work, but for such Tenant Delay.

(iii)Punchlist. Promptly following Substantial Completion of Landlord's Work, Landlord shall provide Tenant with a punchlist prepared by Landlord's architect (the "**Punchlist**") incorporating those items jointly identified by Landlord and Tenant during their joint inspection of Landlord's Work, of outstanding items (the "**Punchlist Items**"). Promptly after Substantial Completion of Landlord's Work, Landlord and Tenant shall jointly inspect the Premises. Subject to Force Majeure (as defined in Section 25.16) and Tenant Delays, Landlord shall complete all Punchlist Items within thirty (30) days of the date of the Punchlist (other than seasonal items, such as landscaping, requiring a longer period), provided that Tenant reasonably cooperates in connection with the completion of such Punchlist Items.

3.3 Tenant's Remedies in the Event of Delays in Term Commencement Date. This Section 3.3 sets forth Tenant's sole remedies, both at law and in equity, in the event of any delay in Landlord's Work or the applicable Term Commencement Date: If the Phase I Term Commencement Date has not occurred on or before the date that is ninety (90) days after the Phase I Estimated Term Commencement Date or if the Phase II Term Commencement Date has not occurred on or before the date that is ninety (90) days after the Phase II Estimated Term Commencement Date (each such date being hereinafter referred to as the "**First Outside Rent Credit Date**"), then, as Tenant's sole remedy, based upon any delay in the applicable Term Commencement Date, Tenant shall be entitled to a rent credit against Tenant's obligation to pay Base Rent for the applicable portion of the Premises (i.e., the Phase I Premises or the Phase II Premises) equal to one (1) day for each day between the First Outside Rent Credit Date and the earlier of (x) the applicable Term Commencement Date and (y) the date that is ninety (90) days

after the applicable First Outside Rent Credit Date (each such date being hereinafter referred to as the "**Second Outside Rent Credit Date**"). If the applicable Term Commencement Date has not occurred on or before the Second Outside Rent Credit Date, as Tenant's sole remedy, Tenant shall be entitled to a rent credit against Tenant's obligation to pay Base Rent for the applicable portion of the Premises equal to two (2) days for each day between the Second Outside Rent Credit Date and the applicable Term Commencement Date. Notwithstanding anything to the contrary contained herein, each of the First Outside Rent Credit Date and the Second Outside Rent Credit Date shall be extended by the length of any delays in Landlord's Work arising from delay by Force Majeure (as defined in Section 25.16) and/or Tenant Delay.

4. USE OF PREMISES

4.1Permitted Uses. During the Term, Tenant shall use the Premises only for the Permitted Uses and for no other purposes. Service and utility areas (whether or not a part of the Premises) shall be used only for the particular purpose for which they are designed. Tenant shall keep the Premises equipped with appropriate safety appliances to the extent required by applicable laws or insurance requirements.

4.2Prohibited Uses.

(a) Notwithstanding any other provision of this Lease, Tenant shall not use the Premises or the Building, or any part thereof, or suffer or permit the use or occupancy of the Premises or the Building or any part thereof by any of the Tenant Parties (i) in a manner which would violate any of the covenants, agreements, terms, provisions and conditions of this Lease or otherwise applicable to or binding upon the Premises; (ii) for any unlawful purposes or in any unlawful manner; (iii) which, in the reasonable judgment of Landlord (taking into account the use of the Building as a combination laboratory, research and development and office building and the Permitted Uses) shall (a) impair the appearance or reputation of the Building; (b) impair, interfere with or otherwise diminish the quality of any of the Building services or the proper and economic heating, cleaning, ventilating, air conditioning or other servicing of the Building or Premises, or the use or occupancy of any of the Common Areas; (c) occasion discomfort, inconvenience or annoyance in any material respect (and Tenant shall not install or use any electrical or other equipment of any kind (including, without limitation, Tenant's Penthouse Equipment) which, in the reasonable judgment of Landlord, will cause any such impairment, interference, discomfort, inconvenience, annoyance or injury), or cause any injury or damage to any occupants of the Premises or other tenants or occupants of the Building or their property; or (d) cause harmful air emissions, laboratory odors or noises or any unusual or other objectionable odors, noises or emissions to emanate from the Premises; (iv) in a manner which is inconsistent with the operation and/or maintenance of the Building as a first-class combination office, research, development and laboratory facility; (v) for any fermentation processes whatsoever; or (vi) in a manner which shall increase such insurance rates on the Building or on property located therein over that applicable when Tenant first took occupancy of the Premises hereunder.

(b) With respect to the use and occupancy of the Premises and the Common Areas, Tenant will not: (i) place or maintain any signage (except as set forth in Section 12.2 below), trash, refuse or other articles in any vestibule or entry of the Premises, on the footwalks or corridors adjacent thereto or elsewhere on the exterior of the Premises, nor obstruct any driveway, corridor, footwalk, parking area, mall or any other Common Areas; (ii) permit undue accumulations of or burn garbage, trash, rubbish or other refuse within or without the Premises;

(iii) permit the parking of vehicles so as to interfere with (x) the ability of others, entitled thereto, to park in the common parking areas, or (y) the use of any driveway, corridor, footwalk, parking area, or other Common Areas; (iv) receive or ship articles of any kind outside of those areas reasonably designated by Landlord; (v) conduct or permit to be conducted any auction, going out of business sale, bankruptcy sale (unless directed by court order), or other similar type sale in or connected with the Premises; (vi) use the name of Landlord, or any of Landlord's affiliates in any publicity, promotion, trailer, press release, advertising, printed, or display materials without Landlord's prior written consent; or (vii) except in connection with Alterations (hereinafter defined) approved by Landlord, cause or permit any hole to be drilled or made in any part of the Building.

4.3MWRA Permit. Landlord shall obtain and maintain with respect to the Common Acid Neutralization Tank, an MWRA waste water discharge permit for the Building. In addition, to the extent required to be obtained by Tenant pursuant to Legal Requirements, Tenant shall establish and maintain with respect to its use of wastewater facilities and discharge to the Common Acid Neutralization Tank, an MWRA waste water discharge program administered by a licensed, qualified individual (which individual may be (i) a third party contractor/consultant approved by Landlord, which approval shall not be unreasonably withheld, or (ii) an employee of Tenant or Tenant's affiliate) in accordance with the requirements of the Massachusetts Water Resources Authority ("**MWRA**") and any other applicable governmental authority. Tenant shall be solely responsible for all costs incurred in connection with its MWRA waste water discharge, and Tenant shall provide Landlord with such documentation as Landlord may reasonably require evidencing Tenant's compliance with the requirements of (a) the MWRA and any other applicable governmental authority with respect to such chemical safety program and (b) this Section. To the extent required to be obtained by Tenant pursuant to Legal Requirements, Tenant, at its sole cost and expense, shall obtain and maintain during the Term any permit required by the MWRA. Tenant shall not introduce anything into the Common Acid Neutralization Tank serving the Premises, if any (x) in violation of the terms of any MWRA permit or any related permit held by Landlord, (y) in violation of Legal Requirements or (z) that would interfere with the proper functioning of the Common Acid Neutralization Tank.

4.4Parking and Traffic Demand Management Plan; Site Action Plan. The Property is subject to a Parking and Traffic Demand Management Plan with the City of Cambridge for the Campus, a copy of which is attached hereto as Exhibit 11 (the "**Initial PTDM**"). Tenant agrees, at its sole expense, to comply with the requirements of the Initial PTDM, only insofar as they apply to the Premises and/or Tenant's use and occupancy thereof. In the event that the Initial PTDM is ever modified, supplemented, amended or replaced ("**PTDM Modifications**"), Tenant agrees, at its sole expense, to comply with the requirements of the PTDM Modifications, only insofar as they apply to the Premises and/or Tenant's use and occupancy thereof. The Parties acknowledge that the Initial PTDM includes requirements that (i) Tenant provide its employees

with a 100% transit subsidy per month in amount up to the federal pre-tax benefit limit and (ii) Landlord charge for parking spaces at the market rate for parking spaces in the Alewife area. Tenant is hereby notified that the Property is subject to a Site Action Plan with the City of Cambridge for Campus in connection with flood risk at the Campus.

4.5Vivarium. Provided that Tenant, at its sole expense, obtains all governmental permits and approvals required therefor, Tenant shall have the right to install a vivarium in the Premises as part of the Tenant Improvement Work or in accordance with the terms and conditions of Article 11 below. Tenant shall be responsible, at its sole expense, for the operations of the vivarium in accordance with all Legal Requirements and with standard industry practices. Without limiting the general application of the foregoing, Tenant shall separately dispose of all waste products from the operation of the vivarium, including, without limitation, dead animals, strictly in accordance with Legal Requirements. Landlord shall have the right, from time to time by written notice to Tenant, to promulgate reasonable rules and regulations with respect to the operation of the vivarium so as to minimize any adverse effects that such operation may have on other occupants of the Building, including without limitation, regulations as to noise mitigation.

4.6Transportation of Animals. No animals, animal waste, food or supplies relating to the animals maintained from time to time in the animal storage areas of the Premises shall be transported within the Building except as provided in this Section 4.6. Tenant shall use commercially reasonable efforts to minimize the presence of animals, animal waste, food or supplies relating to the animals within the Common Areas between the hours of 11:00 a.m. and 1:00 p.m. At all times that animals are transported within the Common Areas, they shall be transported in an appropriate cage or other container. At no time shall any animals, animal waste, food or supplies relating to the animals be brought into, transported through, or delivered to the lobby of the Building or be transported within the Building in elevators other than the freight elevator.

5. RENT; ADDITIONAL RENT

5.1Base Rent; Additional Rent. Commencing as of the Rent Commencement Date and continuing thereafter throughout the remainder of the Term, Tenant shall pay Base Rent to Landlord in equal monthly installments, in advance and without demand on the first day of each month for and with respect to such month. Unless otherwise expressly provided herein, the payment of Base Rent, Additional Rent and other charges reserved and covenanted to be paid under this Lease with respect to the Premises (collectively, "**Rent**") shall commence on the Rent Commencement Date, and shall be prorated for any partial months. Rent shall be payable to Landlord or, if Landlord shall so direct in writing, to Landlord's agent or nominee, in lawful money of the United States which shall be legal tender for payment of all debts and dues, public and private, at the time of payment.

5.2Operating Costs.

(a) "**Operating Costs**" shall mean all costs incurred and expenditures of whatever nature made by Landlord in the operation, management, repair, replacement, maintenance and insurance (including, without limitation, environmental liability insurance and property insurance on Landlord-supplied leasehold improvements for tenants, but not property insurance on tenants' equipment) of the Property or allocated to the Property, including without

limitation all costs of labor (wages, salaries, fringe benefits, etc.) up to and including the Director of Property Management, however denominated, any costs for utilities supplied to exterior areas and the Common Areas, and any costs for repair and replacements, cleaning and maintenance of exterior areas and the Common Areas (including, without limitation, the Building's share of common expenses under the Condominium Documents and costs of maintaining and operating the exterior common areas and facilities of the Campus allocable to the Building), related equipment, facilities and appurtenances and HVAC equipment, security services, a management fee in the amount of four percent (4%) of gross Building revenues (increased, if applicable, in accordance with Section 5.2(g)), the costs, including, without limitation, a commercially reasonable rental factor, of Landlord's management office for the Property, which management office may be located outside the Property and which may serve other properties in addition to the Property (in which event such costs shall be equitably allocated among the properties served by such office), all costs of applying and reporting for the Building or any part thereof to seek or maintain certification under the U.S. EPA's Energy Star® rating system, the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar system or standard, the cost of operating any amenities in the Property available to all tenants of the Property and any subsidy provided by Landlord for or with respect to any such amenity, and the Annual Charge-Off (as hereinafter defined) with respect to a Permitted Capital Expenditure (as hereinafter defined). For costs and expenditures made by Landlord in connection with the operation, management, repair, replacement, maintenance and insurance of the Building as a whole, Landlord shall make a reasonable allocation thereof between the retail and non-retail portions of the Building, if applicable. To the extent that particular Operating Costs affect only non-retail portions of the Building, Landlord may make a reasonable adjustment to Tenant's Share in order to allocate such Operating Costs only to tenants occupying the non-retail portions of the Building. The allocation of Operating Costs relating to the Common Areas of the Campus shall be made in accordance with the Condominium Documents. Operating Costs shall not include Excluded Costs (hereinafter defined).

(b) **Capital Expenditures**. Permitted Capital Expenditures (as hereinafter defined) shall only be included in Operating Costs for each fiscal year during the Term to the extent of the Annual Charge-Off, as hereinafter defined, for such fiscal year with respect to such capital expenditure. Operating Costs shall not include any Annual Charge-Off with respect to Excluded Costs, as hereinafter defined. For the purposes hereof:

(i) "**Annual Charge-Off**" means the annual amount of principal and interest payments which would be required to repay a loan in equal monthly installments over the Useful Life, as defined below, of the capital item in question on a direct reduction basis at an annual interest rate equal to the Capital Interest Rate, as defined below, where the initial principal balance is the cost of the capital item in question.

(ii) "**Useful Life**" shall be reasonably determined by Landlord in accordance with generally accepted accounting principles and practices in effect at the time of acquisition of the capital item.

(iii)"**Capital Interest Rate**" shall be defined as an annual rate of either one percentage point over the AA bond rate (Standard & Poor's corporate composite or, if unavailable, its equivalent) as reported in the financial press at the time the capital expenditure is made or, if the capital item is acquired through third-party financing, then the actual (including fluctuating) rate paid by Landlord in financing the acquisition of such capital item.

(c) "**Excluded Costs**" shall be defined as (i) any fixed or percentage ground rent payable to any ground lessor, or any mortgage charges (including interest, principal, points and fees); (ii) brokerage commissions; (iii) salaries of executives and owners not directly employed in the management/operation of the Property; (iv) the cost of work done by Landlord for a particular tenant; (v) the cost of items which, by generally accepted accounting principles, would be capitalized on the books of Landlord or are otherwise not properly chargeable against income, except to the extent such capital item is (A) required by any Legal Requirements, (B) reasonably projected to reduce Operating Costs, or (C) reasonably expected to improve the management and/or operation of the Building; (vi) the costs of Landlord's Work and any contributions made by Landlord to any tenant of the Property in connection with the build-out of its premises; (vii) franchise or income taxes imposed on Landlord; (viii) costs paid directly by individual tenants to suppliers, including tenant electricity, telephone and other utility costs; (ix) increases in premiums for insurance when such increase is caused by the use of the Building by Landlord or any other tenant of the Building; (x) depreciation of the Building; (xi) costs relating to maintaining Landlord's existence as a corporation, partnership or other entity; (xii) advertising and other fees and costs incurred in procuring tenants; (xiii) the cost of any items for which Landlord is reimbursed by insurance, condemnation awards, refund, rebate or otherwise, and any expenses for repairs or maintenance to the extent covered by warranties, guaranties and service contracts; and (xiv) costs incurred in connection with any disputes between Landlord and its employees, between Landlord and Building management, or between Landlord and other tenants or occupants, (xv) Taxes, (xvi) the cost of acquiring sculptures, paintings or other art, and (xvii) the cost of remediating Hazardous Materials from the Building other than Included Hazardous Materials, as hereinafter defined; "**Included Hazardous Materials**" shall be defined as all Hazardous Materials, other than: (A) any material or substance located in the Building on the Execution Date which, as of the Execution Date, is not considered under then existing Legal Requirements, to be Hazardous Material, but which is subsequently determined to be a Hazardous Material by reason of a Legal Requirement which first becomes effective after the Execution Date of this Lease, and(B) any material or substance that is introduced to the Building after the Execution Date which, when introduced to the Building, is not then (i.e., at the time of introduction to the Building) considered, as a matter of any Legal Requirement, to be a Hazardous Material, but which is subsequently determined to be a Hazardous Material by reason of Legal Requirements which first becomes effective after the date of introduction of such material or substance to the Building.

(d) **Payment of Operating Costs**. Commencing as of the Term Commencement Date and continuing thereafter throughout the remainder of the Term of the Lease, Tenant shall pay to Landlord, as Additional Rent, Tenant's Share of Operating Costs. Landlord may make a good faith estimate of Tenant's Share of Operating Costs for any fiscal year or part thereof during the Term, and Tenant shall pay to Landlord, on the Term Commencement Date and on the first (1st) day of each calendar month thereafter, an amount equal to Tenant's Share of Operating Costs for such fiscal year and/or part thereof divided by the number of months therein. Landlord may estimate and re-estimate Tenant's Share of Operating Costs and deliver a copy of

the estimate or re-estimate to Tenant. Thereafter, the monthly installments of Tenant's Share of Operating Costs shall be appropriately adjusted in accordance with the estimations so that, by the end of the fiscal year in question, Tenant shall have paid all of Tenant's Share of Operating Costs as estimated by Landlord. Any amounts paid based on such an estimate shall be subject to adjustment as herein provided when actual Operating Costs are available for each fiscal year. As of the Execution Date, the Property's fiscal year is January 1 - December 31.

(e) **Annual Reconciliation**. Landlord shall, within one hundred twenty (120) days after the end of each fiscal year, deliver to Tenant a reasonably detailed statement of the actual amount of Operating Costs for such fiscal year ("**Year End Statement**"). Failure of Landlord to provide the Year End Statement within the time prescribed shall not relieve Tenant from its obligations hereunder. If the total of such monthly remittances on account of any fiscal year is greater than Tenant's Share of Operating Costs actually incurred for such fiscal year, then, provided no Event of Default has occurred nor any event which, with the passage of time and/or the giving of notice would constitute an Event of Default, Tenant may credit the difference against the next installment of Additional Rent on account of Operating Costs due hereunder, except that if such difference is determined after the end of the Term, Landlord shall refund such difference to Tenant within thirty (30) days after such determination to the extent that such difference exceeds any amounts then due from Tenant to Landlord. If the total of such remittances is less than Tenant's Share of Operating Costs actually incurred for such fiscal year, Tenant shall pay the difference to Landlord, as Additional Rent hereunder, within thirty (30) days of Tenant's receipt of an invoice therefor. Landlord's estimate of Operating Costs for the next fiscal year shall be based upon the Operating Costs actually incurred for the prior fiscal year as reflected in the Year- End Statement plus a reasonable adjustment based upon estimated increases in Operating Costs. The provisions of this Section 5.2(e) shall survive the expiration or earlier termination of this Lease.

(f) **Part Years**. If the Term Commencement Date or the Expiration Date occurs in the middle of a calendar year, Tenant shall be liable for only that portion of the Operating Costs with respect to such calendar year within the Term.

(g) **Gross-Up**. If, during any fiscal year, less than 95% of the Building is occupied by tenants or if Landlord was not supplying all tenants with the services being supplied to Tenant hereunder, actual Operating Costs incurred shall be reasonably extrapolated by Landlord on an item-by-item basis to the reasonable Operating Costs that would have been incurred if the Building was 95% occupied and such services were being supplied to all tenants, and such extrapolated Operating Costs shall, for all purposes hereof, be deemed to be the Operating Costs for such fiscal year. This "gross up" treatment shall be applied only with respect to variable Operating Costs arising from services provided to Common Areas or to space in the Building being occupied by tenants (which services are not provided to vacant space or may be provided only to some tenants) in order to allocate equitably such variable Operating Costs to the tenants receiving the benefits thereof.

5.3Taxes.

(a) "**Taxes**" shall mean the real estate taxes and other taxes, levies and assessments imposed upon the Unit of the Condominium in which the Building and the Land are located (the "**Unit**") and upon any personal property of Landlord used in the operation thereof, or on Landlord's interest therein or such personal property; charges, fees and assessments for transit, housing, police, fire or other services or purported benefits to the Building and the Land (including without limitation any community preservation assessments); service or user payments in lieu of taxes; and any and all other taxes, levies, betterments, assessments and charges arising from the ownership, leasing, operation, use or occupancy of the Building and the Land or based upon rentals derived therefrom, which are or shall be imposed by federal, state, county, municipal or other governmental authorities. Taxes shall not include any inheritance, estate, succession, gift, franchise, rental, income or profit tax, capital stock tax, capital levy or excise, or any income taxes arising out of or related to the ownership and operation of the Unit, provided, however, that any of the same and any other tax, excise, fee, levy, charge or assessment, however described, that may in the future be levied or assessed as a substitute for or an addition to, in whole or in part, any tax, levy or assessment which would otherwise constitute Taxes, whether or not now customary or in the contemplation of the parties on the Execution Date of this Lease, shall constitute Taxes, but only to the extent calculated as if the Unit were the only real estate owned by Landlord. "Taxes" shall also include reasonable expenses (including without limitation legal and consultant fees) of tax abatement or other proceedings contesting assessments or levies.

Prior to the fiscal year in which the Unit has been created and assessed (the "**Applicable Fiscal Year**"), Landlord shall allocate Taxes which are incurred with respect to the Common Areas of the Campus on a reasonable basis. From and after substantial completion of any occupiable improvements constructed as part of a Future Development, if such improvements are not separately assessed, Landlord shall reasonably allocate Taxes between the Building and such improvements and the land area associated with the same. From and after the Applicable Fiscal Year, such allocation shall be effected based upon the Taxes payable by Landlord with respect to the unit in the Condominium in which the Property is located.

(b) "**Tax Period**" shall be any fiscal/tax period in respect of which Taxes are due and payable to the appropriate governmental taxing authority (i.e., as mandated by the governmental taxing authority), any portion of which period occurs during the Term of this Lease.

(c) **Payment of Taxes**. Commencing as of the Term Commencement Date and continuing thereafter throughout the remainder of the Term of the Lease, Tenant shall pay to Landlord, as Additional Rent, Tenant's Share of Taxes. Landlord may make a good faith estimate of the Taxes to be due by Tenant for any Tax Period or part thereof during the Term, and Tenant shall pay to Landlord, on the Term Commencement Date and on the first (1st) day of each calendar month thereafter, an amount equal to Tenant's Share of Taxes for such Tax Period or part thereof divided by the number of months therein. Landlord may estimate and re-estimate Tenant's Share of Taxes and deliver a copy of the estimate or re-estimate to Tenant. Thereafter, the monthly installments of Tenant's Share of Taxes shall be appropriately adjusted in accordance with the estimations so that, by the end of the Tax Period in question, Tenant shall have paid all of Tenant's Share of Taxes as estimated by Landlord. Any amounts paid based on such an estimate shall be subject to adjustment as herein provided when actual Taxes are available for each Tax Period. If

the total of such monthly remittances is greater than Tenant's Share of Taxes actually due for such Tax Period, then, provided no Event of Default has occurred nor any event which, with the passage of time and/or the giving of notice would constitute an Event of Default, Tenant may credit the difference against the next installment of Additional Rent on account of Taxes due hereunder, except that if such difference is determined after the end of the Term, Landlord shall refund such difference to Tenant within thirty (30) days after such determination to the extent that such difference exceeds any amounts then due from Tenant to Landlord. If the total of such remittances is less than Tenant's Share of Taxes actually due for such Tax Period, Tenant shall pay the difference to Landlord, as Additional Rent hereunder, within ten (10) days of Tenant's receipt of an invoice therefor. Landlord's estimate for the next Tax Period shall be based upon actual Taxes for the prior Tax Period plus a reasonable adjustment based upon estimated increases in Taxes. The provisions of this Section 5.3(c) shall survive the expiration or earlier termination of this Lease.

(d) **Effect of Abatements**. Appropriate credit against Taxes shall be given for any refund obtained by reason of a reduction in any Taxes by the assessors or the administrative, judicial or other governmental agency responsible therefor after deduction of Landlord's expenditures for reasonable legal fees and for other reasonable expenses incurred in obtaining the Tax refund. Upon request by Tenant, Landlord agrees to consult with Tenant in connection with tax protest filings and proceedings undertaken by Landlord to obtain a Tax refund or abatement.

(e) **Part Years**. If the Term Commencement Date or the Expiration Date occurs in the middle of a Tax Period, Tenant shall be liable for only that portion of the Taxes, as the case may be, with respect to such Tax Period within the Term.

5.4Late Payments.

(a) Any payment of Rent due hereunder not paid when due shall bear interest for each month or fraction thereof from the due date until paid in full at the annual rate of eighteen percent (18%), or at any applicable lesser maximum legally permissible rate for debts of this nature (the "**Default Rate**").

(b) Additionally, if Tenant fails to make any payment within five (5) days after the due date therefor, Landlord may charge Tenant a fee, which shall constitute liquidated damages, equal to three percent (3%) of any such late payment, provided, however, Landlord shall waive the late fee once in any twelve-(12)-month period in the event Tenant shall pay such late payment within five (5) days after notice from Landlord.

(c) For each Tenant payment check to Landlord that is returned by a bank for any reason, Tenant shall pay a returned check charge equal to the amount as shall be customarily charged by Landlord's bank at the time.

(d) Money paid by Tenant to Landlord shall be applied to Tenant's account in the following order: first, to any unpaid Additional Rent, including without limitation late charges, returned check charges, legal fees and/or court costs chargeable to Tenant hereunder; and then to unpaid Base Rent.

(e) The parties agree that the late charge referenced in Section 5.4(b) represents a fair and reasonable estimate of the costs that Landlord will incur by reason of any late payment by Tenant, and the payment of late charges and interest are distinct and separate in that the payment of interest is to compensate Landlord for the use of Landlord's money by Tenant, while the payment of late charges is to compensate Landlord for Landlord's processing, administrative and other costs incurred by Landlord as a result of Tenant's delinquent payments. Acceptance of a late charge or interest shall not constitute a waiver of Tenant's default with respect to the overdue amount or prevent Landlord from exercising any of the other rights and remedies available to Landlord under this Lease or at law or in equity now or hereafter in effect.

(f) If Tenant during any six (6) month period shall be more than five (5) days delinquent in the payment of any installment of Rent on three (3) or more occasions, then, notwithstanding anything herein to the contrary, Landlord may, by written notice to Tenant, elect to require Tenant to pay all Base Rent and Additional Rent on account of Operating Costs and Taxes quarterly in advance. Such right shall be in addition to and not in lieu of any other right or remedy available to Landlord hereunder or at law on account of Tenant's default hereunder.

5.5No Offset; Independent Covenants; Waiver. Rent shall be paid without notice or demand, and without setoff, counterclaim, defense, abatement, suspension, deferment, reduction or deduction, except as expressly provided herein. **TENANT WAIVES ALL RIGHTS (I) TO ANY ABATEMENT, SUSPENSION, DEFERMENT, REDUCTION OR DEDUCTION OF OR FROM RENT, AND (II) TO QUIT, TERMINATE OR SURRENDER THIS LEASE OR THE PREMISES OR ANY PART THEREOF, EXCEPT AS EXPRESSLY PROVIDED HEREIN. TENANT HEREBY ACKNOWLEDGES AND AGREES THAT THE OBLIGATIONS OF TENANT HEREUNDER SHALL BE SEPARATE AND INDEPENDENT COVENANTS AND AGREEMENTS, THAT RENT SHALL CONTINUE TO BE PAYABLE IN ALL EVENTS AND THAT THE OBLIGATIONS OF TENANT HEREUNDER SHALL CONTINUE UNAFFECTED, UNLESS THE REQUIREMENT TO PAY OR PERFORM THE SAME SHALL HAVE BEEN TERMINATED PURSUANT TO AN EXPRESS PROVISION OF THIS LEASE. LANDLORD AND TENANT EACH ACKNOWLEDGES AND AGREES THAT THE INDEPENDENT NATURE OF THE OBLIGATIONS OF TENANT HEREUNDER REPRESENTS FAIR, REASONABLE, AND ACCEPTED COMMERCIAL PRACTICE WITH RESPECT TO THE TYPE OF PROPERTY SUBJECT TO THIS LEASE, AND THAT THIS AGREEMENT IS THE PRODUCT OF FREE AND INFORMED NEGOTIATION DURING WHICH BOTH LANDLORD AND TENANT WERE REPRESENTED BY COUNSEL SKILLED IN NEGOTIATING AND DRAFTING COMMERCIAL LEASES IN MASSACHUSETTS, AND THAT THE ACKNOWLEDGEMENTS AND AGREEMENTS CONTAINED HEREIN ARE MADE WITH FULL KNOWLEDGE OF THE HOLDING IN WESSON V. LEONE ENTERPRISES, INC., 437 MASS. 708 (2002). SUCH ACKNOWLEDGEMENTS, AGREEMENTS AND WAIVERS BY TENANT ARE A MATERIAL INDUCEMENT TO LANDLORD ENTERING INTO THIS LEASE.**

5.6Survival. Any obligations under this Section 5 which shall not have been paid at the expiration or earlier termination of the Term shall survive such expiration or earlier termination and shall be paid when and as the amount of same shall be determined and be due.

6. INTENTIONALLY OMITTED.

7. LETTER OF CREDIT

7.1Amount. Contemporaneously with the execution of this Lease, Tenant shall deliver to Landlord an irrevocable letter of credit (the "**Letter of Credit**") that shall (a) be in the initial amount of $6,265,585.53 (the "**Letter of Credit Amount**"); (b) be issued on the form attached hereto as Exhibit 5; (c) name Landlord as its beneficiary; (d) be drawn on an FDIC insured financial institution reasonably satisfactory to Landlord ("**Approved Issuer**") that both (x) has an office in the greater Boston metropolitan area that will accept presentation of, and pay against, the Letter of Credit and (y) satisfies both the Minimum Rating Agency Threshold and the Minimum Capital Threshold (as those terms are defined below). The "**Minimum Rating Agency Threshold**" shall mean that the issuing bank has outstanding unsecured, uninsured and unguaranteed senior long-term indebtedness that is then rated (without regard to qualification of such rating by symbols such as "+" or "-" or numerical notation) "Baa" or better by Moody's Investors Service, Inc. and/or "BBB" or better by Standard & Poor's Rating Services, or a comparable rating by a comparable national rating agency designated by Landlord in its discretion. The "**Minimum Capital Threshold**" shall mean that the issuing bank has combined capital, surplus and undivided profits of not less than $10,000,000,000. The Letter of Credit (and any renewals or replacements thereof) shall be for a term of not less than one (1) year. If the issuer of the Letter of Credit gives notice of its election not to renew such Letter of Credit for any additional period, Tenant shall be required to deliver a substitute Letter of Credit satisfying the conditions hereof at least thirty (30) days prior to the expiration of the term of such Letter of Credit. If the issuer of the Letter of Credit fails to satisfy either or both of the Minimum Rating Agency Threshold or the Minimum Capital Threshold, Tenant shall be required to deliver a substitute letter of credit from another issuer reasonably satisfactory to the Landlord and that satisfies both the Minimum Rating Agency Threshold and the Minimum Capital Threshold not later than ten (10) business days after Landlord notifies Tenant of such failure. Tenant agrees that it shall from time to time, as necessary, whether as a result of a draw on the Letter of Credit by Landlord pursuant to the terms hereof or as a result of the expiration of the Letter of Credit then in effect, renew or replace the original and any subsequent Letter of Credit so that a Letter of Credit, in the amount required hereunder, is in effect until a date which is at least sixty (60) days after the Expiration Date. If Tenant fails to furnish such renewal or replacement at least sixty (60) days prior to the stated expiration date of the Letter of Credit then held by Landlord, Landlord may draw upon such Letter of Credit and hold the proceeds thereof (and such proceeds need not be segregated) as a Security Deposit pursuant to the terms of this Article 7. Any renewal or replacement of the original or any subsequent Letter of Credit shall meet the requirements for the original Letter of Credit as set forth above, except that such replacement or renewal shall be issued by an Approved Issuer.

7.2Application of Proceeds of Letter of Credit. Upon an Event of Default, or if any proceeding shall be instituted by or against Tenant pursuant to any of the provisions of any Act of Congress or State law relating to bankruptcy, reorganizations, arrangements, compositions or other relief from creditors (and, in the case of any proceeding instituted against it, if Tenant shall fail to have such proceedings dismissed within ninety (90) days) or if Tenant is adjudged bankrupt or insolvent as a result of any such proceeding, Landlord at its sole option may draw down all or a part of the Letter of Credit. The balance of any Letter of Credit cash proceeds shall be held in accordance with Section 7.5 below. Should the entire Letter of Credit, or any portion thereof, be drawn down by Landlord, Tenant shall, upon the written demand of Landlord, deliver a replacement Letter of Credit in the amount drawn, and Tenant's failure to do so within ten (10) business days after receipt of such written demand shall constitute an additional Event of Default hereunder. The application of all or any part of the cash proceeds of the Letter of Credit to any obligation or default of Tenant under this Lease shall not deprive Landlord of any other rights or remedies Landlord may have nor shall such application by Landlord constitute a waiver by Landlord.

7.3Transfer of Letter of Credit. In the event that Landlord transfers its interest in the Premises, Tenant shall upon notice from and at no cost to Landlord, deliver to Landlord an amendment to the Letter of Credit or a replacement Letter of Credit naming Landlord's successor as the beneficiary thereof. If Tenant fails to deliver such amendment or replacement within ten (10) days after written notice from Landlord, Landlord shall have the right to draw down the entire amount of the Letter of Credit and hold the proceeds thereof in accordance with Section 7.5 below.

7.4Cash Proceeds of Letter of Credit. Landlord shall hold the balance of proceeds remaining after a draw on the Letter of Credit (each hereinafter referred to as the "**Security Deposit**") as security for Tenant's performance of all its Lease obligations. After an Event of Default, Landlord may apply the Security Deposit, or any part thereof, to Landlord's damages without prejudice to any other Landlord remedy. Landlord has no obligation to pay interest on the Security Deposit and may co-mingle the Security Deposit with Landlord's funds. If Landlord conveys its interest under this Lease, the Security Deposit, or any part not applied previously, may be turned over to the grantee in which case Tenant shall look solely to the grantee for the proper application and return of the Security Deposit.

7.5Return of Security Deposit or Letter of Credit. Should Tenant comply with all of such terms, covenants and conditions and promptly pay all sums payable by Tenant to Landlord hereunder, the Security Deposit and/or Letter of Credit or the remaining proceeds therefrom, as applicable, shall (less any portion thereof which may have been utilized by Landlord to cure any default or applied to any actual damage suffered by Landlord) be returned to Tenant within sixty (60) days after the end of the Term.

7.6Reduction in Letter of Credit Amount. If Tenant satisfies the Reduction Conditions, as hereinafter defined, then, subject to the provisions of this Section 7.6, the Letter of Credit Amount shall be reduced to $2,784,704.67 (the "**Reduced Letter of Credit Amount**") as of the Reduction Date, as hereinafter defined. For the purposes hereof, the "**Reduction Conditions**" shall be deemed to be satisfied by Tenant, if all of the following occur: (x) Tenant is in full compliance with Tenant's obligations under the Lease as of the Reduction Date, (y) there has been no Event of Default by Tenant prior to the Reduction Date, and (z) Tenant has a market

capitalization of at least Five Billion and 00/100 Dollars ($5,000,000,000.00) for four (4) consecutive fiscal quarters immediately preceding and as of the Reduction Date, as evidenced by supporting documentation reasonably acceptable to Landlord. The "**Reduction Date**" means the date that Tenant first satisfies all of the Reduction Conditions, provided, however, that such date shall in no event be earlier than the last day of Rent Year 3. Any such reduction in the Letter of Credit Amount shall be effected within ten (10) business days of Tenant's written request made after the Reduction Date. The reduction in the Letter of Credit Amount may be effected by either, at Tenant's election, Tenant's delivering to Landlord: (i) a new Letter of Credit complying with the provisions of this Section 7, in the Reduced Letter of Credit Amount in exchange for the Letter of Credit which is then being held by Landlord; or (ii) an amendment to the Letter of Credit then being held by Landlord, in a form reasonably satisfactory to Landlord, from the bank issuing such Letter of Credit, reflecting the Reduced Letter of Credit Amount.

8. INTENTIONALLY OMITTED.

9. UTILITIES, LANDLORD'S SERVICES

9.1Electricity. Landlord shall contract with the utility provider for electric service to the Property, including the Premises. Commencing on the Term Commencement Date, Tenant shall pay all charges for electricity furnished to the Premises and any equipment exclusively serving the Premises, as Additional Rent, as measured by a submeter, with such metering equipment to be installed as part of the Tenant Improvement Work. At Tenant's request, Landlord shall provide Tenant with reasonable back-up documentation regarding the total charges and the method of allocating the charges to Tenant. Tenant shall, at Tenant's sole cost and expense, maintain and keep in good order, condition and repair the metering equipment used to measure electricity furnished to the Premises and any equipment exclusively serving the same.

9.2Water. Landlord shall contract with the utility provider for water service to the Property, including the Premises. Except as otherwise provided below, the cost of providing water service to the Premises and all other portions of the Building (including, without limitation, the premises of other tenants or occupants of the Building) shall be included in Operating Costs. Notwithstanding the foregoing, if Landlord determines that Tenant is using water in excess of its proportionate share (by floor area) of the total water usage in the Building, Landlord may elect, at Tenant's expense, to furnish and install in a location in or near the Premises metering equipment to measure water furnished to the Premises and any equipment exclusively serving the same. In such event, Tenant shall, within thirty (30) days after Landlord's written demand therefor from time to time, pay to Landlord, as Additional Rent, the full amount of any water service charges attributable to such meter.

9.3Gas. Landlord shall contract with the utility provider for gas service to the Property, including the Premises. The cost of gas used to serve base building plumbing, mechanical and electrical systems shall be included in the costs reimbursed by Tenant pursuant to Section 9.6 below. If Tenant requires gas service for the operation of Tenant's laboratory equipment in the Premises, Tenant shall pay all charges for gas furnished to the Premises and/or any equipment exclusively serving the Premises as Additional Rent, based, at Landlord's election, (i) on Landlord's reasonable estimate of such gas usage or (ii) on metering or submetering equipment installed by Landlord at Tenant's expense.

9.4Other Utilities. Subject to Landlord's reasonable rules and regulations governing the same, Tenant shall obtain and pay, as and when due, for all other utilities and services consumed in and/or furnished to the Premises, together with all taxes, penalties, surcharges and maintenance charges pertaining thereto.

9.5Interruption or Curtailment of Utilities. When necessary by reason of accident or emergency, or for repairs, alterations, replacements or improvements which in the reasonable judgment of Landlord are desirable or necessary to be made, Landlord reserves the right, upon as much prior notice to Tenant as is practicable under the circumstances and no less than twenty-four

(24) hours' notice except in the event of an emergency, to interrupt, curtail, or stop (i) the furnishing of hot and/or cold water, and (ii) the operation of the plumbing and electric systems. Landlord shall exercise reasonable diligence to eliminate the cause of any such interruption, curtailment, stoppage or suspension, but, except as set forth in Section 10.7, there shall be no diminution or abatement of Rent or other compensation due from Landlord to Tenant hereunder, nor shall this Lease be affected or any of Tenant's obligations hereunder reduced, and Landlord shall have no responsibility or liability for any such interruption, curtailment, stoppage, or suspension of services or systems.

9.6Landlord's Services. Subject to reimbursement pursuant to Section 5.2 above, Landlord shall provide the services described in Exhibit 6 attached hereto and made a part hereof ("**Landlord's Services**"). Except for the cost of providing and maintaining supplemental HVAC equipment exclusively serving the Premises (which shall be Tenant's responsibility), all costs incurred in connection with the provision of Landlord's Services shall be included in Operating Costs pursuant to Section 5.2.

10. MAINTENANCE AND REPAIRS

10.1Maintenance and Repairs by Tenant. Tenant shall keep neat and clean and free of insects, rodents, vermin and other pests and in good repair, order and condition (reasonable wear and tear and damage by Casualty excepted): the Premises, including without limitation the entire interior of the Premises, all electronic, phone and data cabling and related equipment (other than building service equipment) that is installed by or for the exclusive benefit of the Tenant (whether located in the Premises or other portions of the Building), all fixtures, equipment and specialty lighting therein, any supplemental HVAC and humidification equipment exclusively serving the Premises, electrical equipment wiring, doors, non-structural walls, windows and floor coverings, and all laboratory specific systems and equipment that exclusively serve the Premises, including, without limitation, equipment critical to laboratory operations. Without limiting the foregoing, Tenant agrees that it shall maintain in the same repair, order, and condition as on the Term Commencement Date (reasonable wear and tear and damage by Casualty excepted) any equipment installed is the Premises or Building by or on behalf of Tenant (including as part of the Tenant Improvement Work).

10.2Maintenance and Repairs by Landlord. Except as otherwise provided in Section 15, and subject to Tenant's obligations in Section 10.1 above, Landlord shall maintain and keep in reasonable condition (1) the Building foundation, the roof, Building structure, the common mechanical systems serving the Building, the structural floor slabs and columns, and (2) the facilities of the Building, including the base building mechanical, electrical, plumbing, sprinkler, fire/life safety, and access control systems and the base building heating, ventilating, and air conditioning systems serving the Building and other common Building systems equipment serving the Premises, as may be necessary to keep them in good order, repair, and condition. In addition, Landlord shall operate and maintain the Common Areas in substantially the same manner as comparable combination office and laboratory facilities in the vicinity of the Premises. All costs incurred by Landlord under this Section 10.2 shall be included in Operating Costs, subject to, and in accordance with Section 5.2.

10.3Accidents to Sanitary and Other Systems. Tenant shall give to Landlord prompt notice of any fire or accident in the Premises or in the Building and of any damage to, or defective condition in, any part or appurtenance of the Building including, without limitation, sanitary, electrical, ventilation, heating and air conditioning or other systems located in, or passing through, the Premises. Except as otherwise provided in Section 15, and subject to Tenant's obligations in Section 10.1 above, such damage or defective condition shall be remedied by Landlord with reasonable diligence, but, subject to Section 14.5 below, if such damage or defective condition was caused by any of the Tenant Parties, the cost to remedy the same shall be paid by Tenant.

10.4Floor Load--Heavy Equipment. Tenant shall not place a load upon any floor of the Premises exceeding the floor load per square foot of area which such floor was designed to carry and which is allowed by Legal Requirements. Landlord reserves the right to prescribe the weight and position of all safes, heavy machinery, heavy equipment, freight, bulky matter or fixtures (collectively, "**Heavy Equipment**"), which shall be placed so as to distribute the weight. Heavy Equipment shall be placed and maintained by Tenant at Tenant's expense in settings sufficient in Landlord's reasonable judgment to absorb and prevent vibration, noise and annoyance. Tenant shall not move any Heavy Equipment into or out of the Building without giving Landlord prior written notice thereof and observing all of Landlord's Rules and Regulations with respect to the same. If such Heavy Equipment requires special handling, Tenant agrees to employ only persons holding a Master Rigger's License to do said work, and that all work in connection therewith shall comply with Legal Requirements. Any such moving shall be at the sole risk and hazard of Tenant and Tenant will defend, indemnify and save Landlord and Landlord's agents (including without limitation its property manager), contractors and employees (collectively with Landlord, the "**Landlord Parties**") harmless from and against any and all claims, damages, losses, penalties, costs, expenses and fees (including without limitation reasonable legal fees) (collectively, "**Claims**") resulting directly or indirectly from such moving. Proper placement of all Heavy Equipment in the Premises shall be Tenant's responsibility.

10.5Premises Cleaning. Tenant shall be responsible, at its sole cost and expense, for janitorial and trash removal services and other biohazard disposal services for the Premises, including the laboratory areas thereof. Such services shall be performed by licensed (where required by law or governmental regulation), insured and qualified contractors approved in advance, in writing, by Landlord (which approval shall not be unreasonably withheld, delayed or conditioned) and on a sufficient basis to ensure that the Premises are at all times kept neat and

clean. Landlord shall provide a dumpster and/or compactor at the Building loading dock for Tenant's disposal of non-hazardous and non-controlled substances. All costs incurred by Landlord in connection with such dumpster and/or compactor shall be included in Operating Costs as provided in Section 5.2.

10.6Pest Control. Tenant, at Tenant's sole cost and expense, shall cause the Premises to be exterminated on a monthly basis to Landlord's reasonable satisfaction and shall cause all portions of the Premises used for the storage, preparation, service or consumption of food or beverages to be cleaned daily in a manner reasonably satisfactory to Landlord, and to be treated against infestation by insects, rodents and other vermin and pests whenever there is evidence of any infestation. Tenant shall not permit any person to enter the Premises for the purpose of providing such extermination services, unless such persons have been approved by Landlord. If requested by Landlord, Tenant shall, at Tenant's sole cost and expense, store any refuse generated in the Premises by the consumption of food or beverages in a cold box or similar facility.

10.7 Service Interruptions.

(a) Abatement of Rent. In the event that: (i) there shall be an interruption, curtailment or suspension of any service or failure to perform any obligation required to be provided or performed by Landlord pursuant to Sections 9 and/or 10 (and no reasonably equivalent alternative service or supply is provided by Landlord) that shall materially interfere with Tenant's use and enjoyment of the Premises, or any portion thereof (any such event, a "**Service Interruption**"), and (ii) such Service Interruption shall continue for five (5) consecutive business days following receipt by Landlord of written notice (the "**Service Interruption Notice**") from Tenant describing such Service Interruption ("**Abatement Service Interruption Cure Period**"), and (iii) such Service Interruption shall not have been caused by an act or omission of Tenant or Tenant's agents, employees, contractors or invitees (an event that satisfies the foregoing conditions (i)-(iii) being referred to hereinafter as a "**Material Service Interruption**") then, Tenant, subject to the next following sentence, shall be entitled to an equitable abatement of Base Rent, Operating Costs and Taxes based on the nature and duration of the Material Service Interruption and the area of the Premises affected, for any and all days following the Material Service Interruption Cure Period that both (x) the Material Service Interruption is continuing and (y) Tenant does not use such affected areas of the Premises for a bona fide business purpose. Any efforts by Tenant to respond or react to any Material Service Interruption, including, without limitation, any activities by Tenant to remove its personal property from the affected areas of the Premises, shall not constitute a use that precludes abatement pursuant to this Section 10.7(a). The Abatement Service Interruption Cure Period shall be extended by reason of any delays in Landlord's ability to cure the Service Interruption in question caused by Force Majeure.

(b) The provisions of this Section 10.7 shall not apply in the event of a Service Interruption caused by Casualty or Taking (see Section 15 below).

(c) The provisions of this Section 10.7 set forth Tenant's sole rights and remedies, both in law and in equity, in the event of any Service Interruption.

11. ALTERATIONS AND IMPROVEMENTS BY TENANT

11.1 Landlord's Consent Required.

(a) Tenant shall not make any alterations, decorations, installations, removals, additions or improvements (collectively with Tenant's Work, "**Alterations**") in or to the Premises without Landlord's prior written approval of the contractor(s), written plans and specifications and a time schedule therefor. Landlord reserves the right to require that Tenant use Landlord's preferred vendor(s) for any Alterations that involve roof penetrations, alarm tie-ins, sprinklers, fire alarm and other life safety equipment. Tenant shall not make any amendments or additions to plans and specifications approved by Landlord without Landlord's prior written consent. Landlord's approval of non-structural Alterations shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Landlord may withhold its consent in its sole discretion (a) to any Alteration to or affecting the fixed lab benches, fume hoods, roof and/or building systems, (b) with respect to matters of aesthetics relating to Alterations to or affecting the exterior of the Building, and (c) to any Alteration affecting the Building structure. Tenant shall be responsible for all elements of the design of Tenant's plans (including, without limitation, compliance with Legal Requirements, functionality of design, the structural integrity of the design, the configuration of the Premises and the placement of Tenant's furniture, appliances and equipment), and Landlord's approval of Tenant's plans shall in no event relieve Tenant of the responsibility for such design. In seeking Landlord's approval, Tenant shall provide Landlord, at least fourteen (14) business days in advance of any proposed construction, with plans, specifications, bid proposals, certified stamped engineering drawings and calculations by Tenant's engineer of record or architect of record (including connections to the Building's structural system, the Building's mechanical, electrical and plumbing systems, modifications to the Building's envelope, non-structural penetrations in slabs or walls, and modifications or tie-ins to life safety systems), work contracts, requests for laydown areas and such other information concerning the nature and cost of the Alterations as Landlord may reasonably request. Landlord shall have no liability or responsibility for any claim, injury or damage alleged to have been caused by the particular materials (whether building standard or non-building standard), appliances or equipment selected by Tenant in connection with any work performed by or on behalf of Tenant. Except as otherwise expressly set forth herein, all Alterations shall be done at Tenant's sole cost and expense and at such times and in such manner as Landlord may from time to time reasonably designate. If Tenant shall make any Alterations, then, if Landlord, in Landlord's reasonable judgment, determines that the Alterations (i) adversely affect the general utility of the Building for use by prospective tenants thereof, or (ii) require unusual expense to restore and/or redapt the Premises to usual use as a biotechnology office and research and development facility, Landlord may elect to require Tenant at the expiration or sooner termination of the Term to restore the Premises to substantially the same condition as existed immediately prior to the Alterations. Landlord agrees that it will make such election with respect to any Alteration at the time that Landlord approves Tenant's plans and specifications for an Alteration, if Tenant gives written notice to Landlord requesting Landlord to make such election at the time of such approval; provided, however, that in all events, at Landlord's election, Tenant shall be required to remove the Alterations associated with Tenant's vivarium operations in the Premises. Tenant shall provide Landlord with reproducible record drawings (in CAD format) of all Alterations within sixty (60) days after completion thereof.

(b) Alterations Permitted without Landlord's Consent. Notwithstanding anything to the contrary herein contained, Tenant shall have the right without obtaining the prior consent of Landlord, but upon prior notice to Landlord as provided below, to make Alterations to the Premises where: (i) the same are within the interior of the Premises, and do not affect and are not visible from the exterior of the Building, and do not affect any of the Building's systems or the ceiling of the Premises; (ii) the same do not affect the roof or any structural element of the Building, or the fire protection systems of the Building; (iii) the same do not create a nuisance and do not interfere with the rights of other tenants located in the Building; (iv) the cost of any such Alterations shall not exceed $100,000.00 in cost per year; (v) Tenant shall comply with the provisions of this Lease, and if such work increases the cost of insurance or taxes, Tenant shall pay for any such increase in cost; and (vi) Tenant gives Landlord at least ten (10) business days' prior notice describing such work in reasonable detail, accompanied by copies of plans and specifications therefor (to the extent plans and specifications are typically prepared in accordance with such work).

11.2After-Hours. Landlord and Tenant recognize that to the extent Tenant elects to perform some or all of the Alterations during times other than normal construction hours (i.e., Monday-Friday, 7:00 a.m. to 3:00 p.m., excluding holidays), Landlord may need to make arrangements to have supervisory personnel on site. Accordingly, Landlord and Tenant agree as follows: Tenant shall give Landlord at least two (2) business days' prior written notice of any time outside of normal construction hours when Tenant intends to perform any Alterations (the "**After- Hours Work**"). Tenant shall reimburse Landlord, within ten (10) days after demand therefor, for the cost of Landlord's supervisory personnel overseeing the After-Hours Work. In addition, if construction during normal construction hours unreasonably disturbs other tenants of the Building, in Landlord's sole discretion, Landlord may require Tenant to stop the performance of Alterations during normal construction hours and to perform the same after hours, subject to the foregoing requirement to pay for the cost of Landlord's supervisory personnel.

11.3Harmonious Relations. Tenant agrees that it will not, either directly or indirectly, use any contractors and/or materials if their use will create any difficulty, whether in the nature of a labor dispute or otherwise, with other contractors and/or labor engaged by Tenant or Landlord or others in the construction, maintenance and/or operation of the Building, the Property or any part thereof. In the event of any such difficulty, upon Landlord's request, Tenant shall cause all contractors, mechanics or laborers causing such difficulty to leave the Property immediately.

11.4Liens. No Alterations shall be undertaken by Tenant until (i) Tenant has made provision for written waiver of liens from all contractors for such Alteration and taken other appropriate protective measures approved and/or required by Landlord; and (ii) Tenant has procured appropriate surety payment and performance bonds which shall name Landlord as an additional obligee and has filed lien bond(s) (in jurisdictions where available) on behalf of such contractors. Any mechanic's lien filed against the Premises or the Building for work claimed to have been done for, or materials claimed to have been furnished to, Tenant shall be discharged by Tenant within ten (10) days thereafter, at Tenant's expense by filing the bond required by law or otherwise.

11.5General Requirements. Unless Landlord and Tenant otherwise agree in writing, Tenant shall (a) procure or cause others to procure on its behalf all necessary permits before undertaking any Alterations in the Premises (and provide copies thereof to Landlord); (b) perform all of such Alterations in a good and workmanlike manner, employing materials of good quality and in compliance with Landlord's construction rules and regulations, all insurance requirements of this Lease, and Legal Requirements; and (c) defend, indemnify and hold the Landlord Parties harmless from and against any and all Claims occasioned by or growing out of such Alterations.

12. SIGNAGE

12.1Restrictions. Tenant shall have the right, at Tenant's expense, to install Building standard signage identifying Tenant's business at the entrance to the Premises, which signage shall be subject to Landlord's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed). Subject to the foregoing, and subject to Section 12.2 below, Tenant shall not place or suffer to be placed or maintained on the exterior of the Premises, or any part of the interior visible from the exterior thereof, any sign, banner, advertising matter or any other thing of any kind (including, without limitation, any hand-lettered advertising), and shall not place or maintain any decoration, letter or advertising matter on the glass of any window or door of the Premises without first obtaining Landlord's written approval. No signs may be put on or in any window or elsewhere if visible from the exterior of the Building.

12.2Exterior Signage.

(a) Subject to the provisions of this Section 12.2(a), for so long as: (x) there is no Event of Default of Tenant, and (y) the Lease is in full force and effect (collectively, the "**Monument Signage Condition**"), then Tenant shall have the right to require Landlord to list, at Landlord's initial cost and expense, Tenant's name ("Tenant's Monument Signage") on the exterior monument sign to be constructed by Landlord (as a part of the Base Building Work) on the Property. Such monument sign shall be a common monument (i.e. other tenant(s) in the Building may have identification signage installed on such monument). The right to the Tenant's Monument Signage granted pursuant to this Section 12.2(a) is personal to Tenant, and may not be exercised by any occupant, subtenant, or other assignee of Tenant, other than an Affiliated Entity or Successor (the parties hereby agreeing that Tenant shall be responsible for the cost of any change in Tenant's Monument Signage). The parties hereby agree that the maintenance and removal of such Tenant's Monument Signage (including, without limitation, the repair and cleaning of the existing monument façade upon removal of Tenant's Monument Signage) shall be performed at Landlord's sole cost and expense, except that Tenant shall be responsible for the cost of any change in Tenant's Monument Signage during the Term of the lease.

(b) If during the Term of this Lease, Landlord permits any other tenant of the Building to erect or install any exterior sign on the Building, then, (x) subject to the provisions of this Section 12.2(b) and (y) for so long as the Monument Signage Condition remains satisfied, Landlord shall permit Tenant, at Tenant's sole cost and expense, to erect or install an exterior sign on the Building ("Tenant's Exterior Sign"), provided all such signs, including without limitation, the design, specifications and location thereof, are subject to Landlord's prior written approval, which approval shall not be unreasonably withheld, conditioned or delayed, and are in keeping with the quality, design and style of the Building. Tenant's Exterior Sign shall be (i) subject to all

Legal Requirements and Tenant's obtaining all required governmental approvals at Tenant's sole cost and expense, and (ii) maintained by Tenant at its sole cost and expense in a first-class and safe condition and appearance. Upon the expiration or earlier termination of this Lease, Tenant shall remove Tenant's Exterior Sign at Tenant's sole cost and expense. Tenant shall reimburse Landlord, within thirty (30) days after demand, from time to time, any costs incurred by Landlord to repair any damage to the Building resulting from the erection, maintenance and removal of Tenant's Exterior Sign.

12.3Building Directory.

Landlord shall list Tenant within the directory in the Building lobby. The initial listing shall be at Landlord's cost and expense, and any changes to such directory listing shall be at Tenant's cost and expense. Tenant shall have the right, at Tenant's cost and expense, to install a Building standard Tenant identification sign at the entrance to the Premises.

13. ASSIGNMENT, MORTGAGING AND SUBLETTING

13.1Landlord's Consent Required. Tenant shall not mortgage or encumber this Lease or in whole or in part whether at one time or at intervals, operation of law or otherwise. Except as expressly otherwise set forth herein, Tenant shall not, without Landlord's prior written consent, assign, sublet, license or transfer this Lease or the Premises in whole or in part whether by changes in the ownership or control of Tenant, or any direct or indirect owner of Tenant, whether at one time or at intervals, by sale or transfer of stock, partnership or beneficial interests, operation of law or otherwise, or permit the occupancy of all or any portion of the Premises by any person or entity other than Tenant's employees (each of the foregoing, a "**Transfer**"). Any purported Transfer made without Landlord's consent, if required hereunder, shall be void and confer no rights upon any third person, provided that if there is a Transfer, Landlord may collect rent from the transferee without waiving the prohibition against Transfers, accepting the transferee, or releasing Tenant from full performance under this Lease. In the event of any Transfer in violation of this Section 13, Landlord shall have the right to terminate this Lease upon thirty (30) days' written notice to Tenant given within sixty (60) days after receipt of written notice from Tenant to Landlord of any Transfer, or within one (1) year after Landlord first learns of the Transfer if no notice is given. No Transfer shall relieve Tenant of its primary obligation as party Tenant hereunder, nor shall it reduce or increase Landlord's obligations under this Lease.

13.2Landlord's Recapture Right.

Subject to Section 13.7 below, Tenant shall, prior to offering or advertising the Premises or any portion thereof for a Transfer, give a written notice (the "**Recapture Notice**") to Landlord which: (i) states that Tenant desires to make a Transfer, (ii) identifies the affected portion of the Premises (the "**Recapture Premises**"), (iii) identifies the period of time (the "**Recapture Period**") during which Tenant proposes to sublet the Recapture Premises, or indicates that Tenant proposes to assign its interest in this Lease, and (iv) offers to Landlord to (x) terminate this Lease with respect to the Recapture Premises (in the case of a proposed assignment of Tenant's interest in this Lease or a subletting for the remainder of the Term of this Lease) or (y) in the event that Tenant shall only propose to sublease all or a portion of the Premises for less than all of the remainder of the Term of this Lease, Landlord shall only have the right to terminate this Lease with respect to

the Recapture Premises during the Recapture Period (i.e., the Term with respect to the Recapture Premises shall be terminated during the Recapture Period and Tenant's rental obligations shall be proportionately reduced), after which this Lease shall be reinstated with respect to the Recapture Premises. Landlord shall have fifteen (15) business days within which to respond to the Recapture Notice.

13.3Standard of Consent to Transfer. If Landlord does not timely give written notice to Tenant accepting a Recapture Offer or declines to accept the same, then Landlord agrees that, subject to the provisions of this Section 13 and provided that Tenant has not previously assigned or subleased more than twenty-five percent (25%) of the Premises, Landlord shall not unreasonably withhold, condition or delay its consent to a Transfer at fair market rent and otherwise on the terms contained in the Recapture Notice to an entity which will use the Premises for the Permitted Uses and, in Landlord's reasonable opinion: (a) has a tangible net worth and other financial indicators sufficient to meet the Transferee's obligations under the Transfer instrument in question; (b) has a business reputation compatible with the operation of a first-class combination laboratory, research, development and office building; and (c) the intended use of such entity does not violate any restrictive use provisions then in effect with respect to space in the Building.

13.4Listing Confers no Rights. The listing of any name other than that of Tenant, whether on the doors of the Premises or on the Building directory, or otherwise, shall not operate to vest in any such other person, firm or corporation any right or interest in this Lease or in the Premises or be deemed to effect or evidence any consent of Landlord, it being expressly understood that any such listing is a privilege extended by Landlord revocable at will by written notice to Tenant.

13.5Profits In Connection with Transfers. Except as for Permitted Transfers, Tenant shall, within thirty (30) days of receipt thereof, pay to Landlord fifty percent (50%) of any rent, sum or other consideration to be paid or given in connection with any Transfer, either initially or over time, after deducting reasonable actual out-of-pocket legal, and brokerage expenses incurred by Tenant and unamortized improvements paid for by Tenant in connection therewith, in excess of Rent hereunder as if such amount were originally called for by the terms of this Lease as Additional Rent.

13.6Prohibited Transfers. Notwithstanding any contrary provision of this Lease, Tenant shall have no right to make a Transfer unless on both (i) the date on which Tenant notifies Landlord of its intention to enter into a Transfer and (ii) the date on which such Transfer is to take effect, Tenant is not in default of any of its obligations under this Lease. Notwithstanding anything to the contrary contained herein, Tenant agrees that in no event shall Tenant make a Transfer to (a) any government agency; (b) any tenant, subtenant or occupant of other space in the Building if Landlord has or expects to have any space in the Building available in the following six (6) months; or (c) any entity with whom Landlord is currently negotiating, or shall have negotiated in the six (6) months immediately preceding such proposed Transfer, for space in the Property.

13.7Exceptions to Requirement for Consent. Notwithstanding anything to the contrary herein contained, Tenant shall have the right, without obtaining Landlord's consent and without giving Landlord a Recapture Notice, to (a) make a Transfer to an Affiliated Entity (hereinafter defined) so long as the transfer to such Affiliated Entity is for legitimate business purposes (and not for the purpose of avoiding the provisions of this Section 13), and (b) assign all of Tenant's interest in and to the Lease to a Successor, provided that prior to or simultaneously with any assignment pursuant to this Section 13.7, such Affiliated Entity or Successor, as the case may be, and Tenant execute and deliver to Landlord an assignment and assumption agreement in form and substance reasonably acceptable to Landlord whereby such Affiliated Entity or Successor, as the case may be, shall agree to be independently bound by and upon all the covenants, agreements, terms, provisions and conditions set forth in the Lease on the part of Tenant to be performed, and whereby such Affiliated Entity or Successor, as the case may be, shall expressly agree that the provisions of this Article 13 shall, notwithstanding such Transfer, continue to be binding upon it with respect to all future Transfers. For the purposes hereof, an "**Affiliated Entity**" shall be defined as any entity which is controlled by, is under common control with, or which controls Tenant. For the purposes hereof, a "**Successor**" shall be defined as any entity into or with which Tenant is merged or with which Tenant is consolidated or which acquires all or substantially all of Tenant's stock or assets, provided that the surviving entity shall have a net worth and other financial indicators sufficient to meet Tenant's obligations hereunder. Tenant shall give Landlord at least ten (10) days' prior written notice of any Permitted Transfer, such notice to include evidence, reasonably satisfactory to Landlord, that the conditions to the Permitted Transfer in question have been satisfied. Transfers to Affiliated Entities and to Successor which are permitted pursuant to this Section 13.7, are referred to collectively herein as "**Permitted Transfers**", and such Affiliated Entities and Successors are referred to herein as "**Permitted Transferees**".

13.8Flagship Subleases. Notwithstanding anything to the contrary herein contained, Tenant shall have the right, upon at least ten (10) days' prior written notice from Tenant to Landlord, without obtaining Landlord's consent, and without giving Landlord a Recapture Notice, to enter into Flagship Subleases, as hereinafter defined. A "**Flagship Sublease**" shall be defined as a sublease or license of Internal Sublet Space, as hereinafter defined, to Flagship Entities, as hereinafter defined, provided however, that: (i) at no time shall more than 18,500 rentable square feet of the Premises, in the aggregate, be subject to Flagship Subleases, and (ii) no sublease or license shall be considered to be a Flagship Sublease if it is entered into for the purposes of avoiding the operation of the provisions of this Article 13 (e.g., without limitation, the requirement of obtaining Landlord's consent to such sublease, Landlord's recapture rights, etc.). A "**Flagship Entity**" shall be defined as any person or entity operating a business which, as of the date that such person or entity first occupies any portion of the Premises pursuant to its Flagship Sublease, has been provided funding from Flagship Pioneering, wholly or in part, but not less than fifty (50%) percent of the total funding received by such person or entity. An "**Internal Sublet Space**" shall consist of an area located in the Premises which has access to the common areas of the Building only through Tenant's reception area on the floor on which the Flagship Entity is located.

14. INSURANCE; INDEMNIFICATION; EXCULPATION

14.1 Tenant's Insurance.

(a) Tenant shall procure, pay for and keep in force throughout the Term (and for so long thereafter as Tenant remains in occupancy of the Premises) commercial general liability insurance insuring Tenant on an occurrence basis against all claims and demands for personal injury liability (including, without limitation, bodily injury, sickness, disease, and death) or damage to property which may be claimed to have occurred from and after the time any of the Tenant Parties shall first enter the Premises, of not less than One Million Dollars ($1,000,000) per occurrence and Two Million Dollars ($2,000,000) in the aggregate annually, and from time to time thereafter shall be not less than such higher amounts, if procurable, as may be reasonably required by Landlord. Tenant shall also carry umbrella liability coverage in an amount of no less than Ten Million Dollars ($10,000,000). Such policy shall also include contractual liability coverage covering Tenant's liability assumed under this Lease, including without limitation Tenant's indemnification obligations. Such insurance policy(ies) shall name Landlord, Landlord's managing agent and persons claiming by, through or under them, if any, as additional insureds.

(b) Tenant shall take out and maintain throughout the Term a policy of fire, vandalism, malicious mischief, extended coverage and so-called "all risk" coverage insurance in an amount equal to one hundred percent (100%) of the replacement cost insuring (i) all items or components of Alterations (collectively, the "**Tenant-Insured Improvements**"), and (ii) all of Tenant's furniture, equipment, fixtures and property of every kind, nature and description related or arising out of Tenant's leasehold estate hereunder, which may be in or upon the Premises or the Building, including without limitation Tenant's Penthouse Equipment (collectively, "**Tenant's Property**"). The insurance required to be maintained by Tenant pursuant to this Section 14.1(b) (referred to herein as "**Tenant Property Insurance**") shall insure the interests of both Landlord and Tenant as their respective interests may appear from time to time.

(c) Tenant shall take out and maintain a policy of business interruption insurance throughout the Term sufficient to cover at least twelve (12) months of Rent due hereunder and Tenant's business losses during such 12-month period.

(d) During periods when any Tenant's Work or Alterations are being performed, Tenant shall maintain, or cause to be maintained, so-called all risk or special cause of loss property insurance or its equivalent and/or builders risk insurance on 100% replacement cost coverage basis, including hard and soft costs coverages. Such insurance shall protect and insure Landlord, Landlord's agents, Tenant and Tenant's contractors, as their interests may appear, against loss or damage by fire, water damage, vandalism and malicious mischief, and such other risks as are customarily covered by so-called all risk or special cause of loss property / builders risk coverage or its equivalent.

(e) Tenant shall procure and maintain at its sole expense such additional insurance as may be necessary to comply with any Legal Requirements.

(f) Tenant shall cause all contractors and subcontractors to maintain during the performance of any Alterations the insurance described in Exhibit 9 attached hereto.

(g) The insurance required pursuant to Sections 14.1(a), (b), (c), (d) and (e) (collectively, "**Tenant's Insurance Policies**") shall be effected with insurers approved by Landlord, with a rating of not less than "A-XI" in the current *Best's Insurance Reports*, and authorized to do business in the Commonwealth of Massachusetts under valid and enforceable policies. Tenant's Insurance Policies shall each provide that it shall not be canceled or modified without at least thirty (30) days' prior written notice to each insured named therein. Tenant's Insurance Policies may include deductibles in an amount no greater than the greater of $25,000 or commercially reasonable amounts. On or before the date on which any of the Tenant Parties shall first enter the Premises and thereafter not less than fifteen (15) days prior to the expiration date of each expiring policy, Tenant shall deliver to Landlord binders of Tenant's Insurance Policies issued by the respective insurers setting forth in full the provisions thereof together with evidence satisfactory to Landlord of the payment of all premiums for such policies. In the event of any claim, and upon Landlord's request, Tenant shall deliver to Landlord complete copies of Tenant's Insurance Policies. Upon request of Landlord, Tenant shall deliver to any Mortgagee copies of the foregoing documents.

14.2Indemnification. Except to the extent caused by the negligence or willful misconduct of any of the Landlord Parties, Tenant shall defend, indemnify and save the Landlord Parties harmless from and against any and all Claims asserted by or on behalf of any person, firm, corporation or public authority arising from:

(a) Tenant's breach of any covenant or obligation under this Lease;

(b) Any injury to or death of any person, or loss of or damage to property, sustained or occurring in, upon or at the Premises;

(c) Any injury to or death of any person, or loss of or damage to property arising out of the use or occupancy of the Premises by or the negligence or willful misconduct of any of the Tenant Parties; and

(d) On account of or based upon any work or thing whatsoever done (other than by Landlord or any of the Landlord Parties) at the Premises during the Term and during the period of time, if any, prior to the Term Commencement Date that any of the Tenant Parties may have been given access to the Premises.

14.3Property of Tenant. Tenant covenants and agrees that, to the maximum extent permitted by Legal Requirements, all of Tenant's Property at the Premises shall be at the sole risk and hazard of Tenant, and that if the whole or any part thereof shall be damaged, destroyed, stolen or removed from any cause or reason whatsoever, no part of said damage or loss shall be charged to, or borne by, Landlord, except, subject to Section 14.5 hereof, to the extent such damage or loss is due to the negligence or willful misconduct of any of the Landlord Parties.

14.4Limitation of Landlord's Liability for Damage or Injury. Landlord shall not be liable for any injury or damage to persons or property resulting from fire, explosion, falling plaster, steam, gas, air contaminants or emissions, electricity, electrical or electronic emanations or disturbance, water, rain or snow or leaks from any part of the Building or from the pipes, appliances, equipment or plumbing works or from the roof, street or sub-surface or from any other place or caused by dampness, vandalism, malicious mischief or by any other cause of whatever nature, except, subject to Section 14.5, to the extent caused by or due to the negligence or willful misconduct of any of the Landlord Parties, and then, where notice and an opportunity to cure are appropriate (i.e., where Tenant has an opportunity to know or should have known of such condition sufficiently in advance of the occurrence of any such injury or damage resulting therefrom as would have enabled Landlord to prevent such damage or loss had Tenant notified Landlord of such condition) only after (i) notice to Landlord of the condition claimed to constitute negligence or willful misconduct, and (ii) the expiration of a reasonable time after such notice has been received by Landlord without Landlord having commenced to take all reasonable and practicable means to cure or correct such condition; and pending such cure or correction by Landlord, Tenant shall take all reasonably prudent temporary measures and safeguards to prevent any injury, loss or damage to persons or property. Notwithstanding the foregoing, in no event shall any of the Landlord Parties be liable for any loss which is covered by insurance policies actually carried or required to be so carried by this Lease; nor shall any of the Landlord Parties be liable for any such damage caused by other tenants or persons in the Building or caused by operations in construction of any private, public, or quasi-public work; nor shall any of the Landlord Parties be liable for any latent defect in the Premises or in the Building.

14.5Waiver of Subrogation; Mutual Release. Landlord and Tenant each hereby waives on behalf of itself and its property insurers (none of which shall ever be assigned any such claim or be entitled thereto due to subrogation or otherwise) any and all rights of recovery, claim, action, or cause of action against the other and its agents, officers, servants, partners, shareholders, or employees (collectively, the "**Related Parties**") for any loss or damage that may occur to or within the Premises or the Building or any improvements thereto, or any personal property of such party therein which is insured against under any Property Insurance (as defined in Section 14.7) policy actually being maintained by the waiving party from time to time, even if not required hereunder, or which would be insured against under the terms of any Property Insurance policy required to be carried or maintained by the waiving party hereunder, whether or not such insurance coverage is actually being maintained, including, in every instance, such loss or damage that may be caused by the negligence of the other party hereto and/or its Related Parties. Landlord and Tenant each agrees to cause appropriate clauses to be included in its Property Insurance policies necessary to implement the foregoing provisions.

14.6Tenant's Acts--Effect on Insurance. Tenant shall not do or permit any Tenant Party to do any act or thing upon the Premises or elsewhere in the Building which will invalidate or be in conflict with any insurance policies covering the Building and the fixtures and property therein; and shall not do, or permit to be done, any act or thing upon the Premises which shall subject Landlord to any liability or responsibility for injury to any person or persons or to property by reason of any business or operation being carried on upon said Premises or for any other reason. If by reason of the failure of Tenant to comply with the provisions hereof the insurance rate applicable to any policy of insurance shall at any time thereafter be higher than it otherwise would be, Tenant shall reimburse Landlord upon demand for that part of any insurance premiums which

shall have been charged because of such failure by Tenant, together with interest at the Default Rate until paid in full, within ten (10) days after receipt of an invoice therefor. In addition, Tenant shall reimburse Landlord for any increase in insurance premium arising as a result of Tenant's use and/or storage of any Hazardous Materials in the Premises.

14.7Landlord's Insurance. Landlord shall carry at all times during the Term of this Lease: (i) commercial general liability insurance with respect to the Building, the Land and the Common Areas thereof in an amount not less than Five Million Dollars ($5,000,000) combined single limit per occurrence, (ii) with respect to the Building, excluding Tenant-Insured Improvements and improvements made by other tenants or occupants, insurance against loss or damage caused by any peril covered under fire, extended coverage and all risk insurance with coverage against vandalism, malicious mischief and such other insurable hazards and contingencies as are from time to time normally insured against by owners of similar first class offices/research/laboratory buildings/campuses in the Market Area or which are required by Landlord's mortgagee, in an amount equal to one hundred percent (100%) of the full replacement cost thereof above foundation walls ("**Landlord Property Insurance**"), and (iii) rent interruption insurance covering at least eighteen (18) months. Any and all such insurance: (x) may be maintained under a blanket policy affecting other properties of Landlord and/or its affiliated business organizations, and (y) may be written with commercially reasonable deductibles as determined by Landlord. The costs incurred by Landlord related to such insurance shall be included in Operating Costs. Tenant Property Insurance and Landlord Property Insurance are referred to collectively herein as "**Property Insurance**".

15. CASUALTY; TAKING

15.1Damage. If the Premises are damaged in whole or part because of fire or other insured casualty ("**Casualty**"), or if the Premises are subject to a taking in connection with the exercise of any power of eminent domain, condemnation, or purchase under threat or in lieu thereof (any of the foregoing, a "**Taking**"), then unless this Lease is terminated in accordance with Section 15.2 below, Landlord shall restore the Building and/or the Premises to substantially the same condition as existed immediately following completion of Landlord's Work, or in the event of a partial Taking which affects the Building and the Premises, restore the remainder of the Building and the Premises not so Taken to substantially the same condition as is reasonably feasible. If, in Landlord's reasonable judgment, any element of the Tenant-Insured Improvements can more effectively be restored as an integral part of Landlord's restoration of the Building or the Premises, such restoration shall also be made by Landlord, but at Tenant's sole cost and expense. Subject to rights of Mortgagees, Tenant Delays, Legal Requirements then in existence and to delays for adjustment of insurance proceeds or Taking awards, as the case may be, and instances of Force Majeure, Landlord shall substantially complete such restoration within one (1) year after Landlord's receipt of all required permits therefor with respect to substantial reconstruction of at least 50% of the Building, or, within one hundred eighty (180) days after Landlord's receipt of all required permits therefor in the case of restoration of less than 50% of the Building. Upon substantial completion of such restoration by Landlord, Tenant shall use diligent efforts to complete restoration of the Premises to substantially the same condition as existed immediately prior to such Casualty or Taking, as the case may be, as soon as reasonably possible. Tenant agrees to cooperate with Landlord in such manner as Landlord may reasonably request to assist Landlord in collecting insurance proceeds due in connection with any Casualty which affects the Premises

or the Building. In no event shall Landlord be required to expend more than the Net (hereinafter defined) insurance proceeds Landlord receives for damage to the Premises and/or the Building or the Net Taking award attributable to the Premises and/or the Building. "**Net**" means the insurance proceeds or Taking award actually paid to Landlord (and not paid over to a Mortgagee) less all costs and expenses, including adjusters and attorney's fees, of obtaining the same. In the Operating Year in which a Casualty occurs, there shall be included in Operating Costs Landlord's deductible under its property insurance policy. Except as Landlord may elect pursuant to this Section 15.1, under no circumstances shall Landlord be required to repair any damage to, or make any repairs to or replacements of, any Tenant-Insured Improvements.

15.2Termination Rights.

(a) Landlord's Termination Rights. Landlord may terminate this Lease upon thirty (30) days' prior written notice to Tenant if:

(i) any material portion of the Building or any material means of access thereto is taken;

(ii) more than thirty-five percent (35%) of the Building is damaged by Casualty; or

(iii)if the estimated time to complete restoration exceeds one (1) year

from the date on which Landlord receives all required permits for such restoration.

(b) Tenant's Termination Right. If Landlord is so required but fails to complete restoration of the Premises within the time frames and subject to the conditions set forth in Section 15.1 above, then Tenant may terminate this Lease upon thirty (30) days' written notice to Landlord; provided, however, that if Landlord completes such restoration within thirty (30) days after receipt of any such termination notice, such termination notice shall be null and void and this Lease shall continue in full force and effect. The remedies set forth in this Section 15.2(b) and in Section 15.2(c) below are Tenant's sole and exclusive rights and remedies based upon Landlord's failure to complete the restoration of the Premises as set forth herein. Notwithstanding anything to the contrary contained herein, Tenant shall not have the right to terminate this Lease pursuant to this Section 15 if the Casualty was caused by the negligence or intentional misconduct of any Tenant Party.

(c) Either Party May Terminate. In the case of any Casualty or Taking affecting the Premises and occurring during the last twelve (12) months of the Term, then (i) if such Casualty or Taking results in more than twenty-five percent (25%) of the floor area of the Premises being unsuitable for the Permitted Uses, or (ii) the damage to the Premises costs more than $250,000 to restore, then either Landlord or Tenant shall have the option to terminate this Lease upon thirty (30) days' written notice to the other. In addition, if Landlord's Mortgagee does not release sufficient insurance proceeds to cover the cost of Landlord's restoration obligations, then Landlord shall (i) notify Tenant thereof, and (ii) have the right to terminate this Lease. If Landlord does not terminate this Lease pursuant to the previous sentence and such notice by Landlord does not include an agreement by Landlord to pay for the difference between the cost of such restoration and such released insurance proceeds, then Tenant may terminate this Lease by written notice to

Landlord on or before the date that is thirty (30) days after such notice. Notwithstanding anything to the contrary contained in this Section 15, in no event may Tenant elect to terminate this Lease hereunder if the Casualty that would otherwise give rise to such right results from the gross negligence or willful misconduct of Tenant, its agents, contractors, or employees.

(d) Automatic Termination. In the case of a Taking of the entire Premises, then this Lease shall automatically terminate as of the date of possession by the Taking authority.

15.3Rent Abatement. In the event of a Casualty affecting the Premises, there shall be an equitable adjustment of Base Rent, Operating Costs and Taxes based upon the degree to which Tenant's ability to conduct its business in the Premises is impaired by reason of such Casualty from and after the date of a Casualty, and continuing until the following portions of the repair and restoration work to be performed by Landlord, as set forth above, are substantially completed: (i) any repair and restoration work to be performed by Landlord within the Premises, and (ii) repair and restoration work with respect to the Common Areas to the extent that damage to the Common Areas caused by such Casualty materially adversely affects Tenant's use of, or access to, the Premises.

15.4Taking for Temporary Use. If the Premises are Taken for temporary use, this Lease and Tenant's obligations, including without limitation the payment of Rent, shall continue. For purposes hereof, a "**Taking for temporary use**" shall mean a Taking of ninety (90) days or less.

15.5Disposition of Awards. Except for any separate award for Tenant's movable trade fixtures, relocation expenses, and unamortized leasehold improvements paid for by Tenant (provided that the same may not reduce Landlord's award), all Taking awards to Landlord or Tenant shall be Landlord's property without Tenant's participation, and Tenant hereby assigns to Landlord Tenant's interest, if any, in such award. Tenant may pursue its own claim against the Taking authority.

16. ESTOPPEL CERTIFICATE.

Tenant shall at any time and from time to time upon not less than ten (10) business days' prior notice from Landlord, execute, acknowledge and deliver to Landlord a statement in writing certifying that this Lease is unmodified and in full force and effect (or if there have been modifications, that the same is in full force and effect as modified and stating the modifications), and the dates to which Rent has been paid in advance, if any, stating whether or not Landlord is in default in performance of any covenant, agreement, term, provision or condition contained in this Lease and, if so, specifying each such default, and such other facts as Landlord may reasonably request, it being intended that any such statement delivered pursuant hereto may be relied upon by Landlord, any prospective purchaser of the Building or of any interest of Landlord therein, any Mortgagee or prospective Mortgagee thereof, any lessor or prospective lessor thereof, any lessee or prospective lessee thereof, or any prospective assignee of any mortgage thereof. *Time is of the essence with respect to any such requested certificate*, Tenant hereby acknowledging the importance of such certificates in mortgage financing arrangements, prospective sales and the like. If Tenant shall fail to execute and deliver to Landlord any such statement within such ten-day

period, Tenant hereby appoints Landlord as Tenant's attorney-in-fact in its name and behalf to execute such statement, such appointment being coupled with an interest.

17. HAZARDOUS MATERIALS

17.1 Prohibition.

(a) Tenant shall not, without the prior written consent of Landlord, bring or permit to be brought or kept in or on the Premises or elsewhere in the Building or the Property (i) any inflammable, combustible or explosive fluid, material, chemical or substance (except for standard office supplies stored in proper containers); and (ii) any Hazardous Material (hereinafter defined), other than the types and quantities of Hazardous Materials which are listed on Exhibit 7 attached hereto ("**Tenant's Hazardous Materials**"), provided that the same shall at all times be brought upon, kept or used in so-called 'control areas' and in accordance with all applicable Legal Requirements, including, without limitation, all applicable Environmental Laws (hereinafter defined); and in accordance with prudent environmental practice and (with respect to medical waste and so-called "biohazard" materials) good scientific and medical practice. Tenant's control areas shall be located in the areas shown on Exhibit 7-1 attached hereto.

(b) Tenant shall be responsible for assuring that all laboratory uses are adequately and properly vented. On or before each anniversary of the Term Commencement Date, and on any earlier date during the twelve (12) month period on which Tenant intends to add a new Hazardous Material or materially increase the quantity of any Hazardous Material to the list of Tenant's Hazardous Materials, Tenant shall submit to Landlord an updated list of Tenant's Hazardous Materials for Landlord's review and approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord shall have the right, from time to time, to inspect the Premises for compliance with the terms of this Section 17.1. Notwithstanding the foregoing, with respect to any of Tenant's Hazardous Materials which Tenant does not properly handle, store or dispose of in compliance with all applicable Environmental Laws (hereinafter defined), prudent environmental practice and (with respect to medical waste and so-called "biohazard materials") good scientific and medical practice, Tenant shall, upon written notice from Landlord, no longer have the right to bring such material into the Building or the Property until Tenant has demonstrated, to Landlord's reasonable satisfaction, that Tenant has implemented programs to thereafter properly handle, store or dispose of such material. In order to induce Landlord to waive its otherwise applicable requirement that Tenant maintain insurance in favor of Landlord against liability arising from the presence of radioactive materials in the Premises, and without limiting the foregoing, Tenant hereby represents and warrants to Landlord that at no time during the Term will Tenant bring upon, or permit to be brought upon, the Premises any radioactive materials whatsoever.

17.2Environmental Laws. For purposes hereof, "**Environmental Laws**" shall mean all laws, statutes, ordinances, rules and regulations of any local, state or federal governmental authority having jurisdiction concerning environmental, health and safety matters, including but not limited to any discharge by any of the Tenant Parties into the air, surface water, sewers, soil or groundwater of any Hazardous Material (hereinafter defined) whether within or outside the Premises, including, without limitation (a) the Federal Water Pollution Control Act, 33 U.S.C. Section 1251 et seq., (b) the Federal Resource Conservation and Recovery Act, 42 U.S.C. Section

6901 et seq., (c) the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. Section 9601 et seq., (d) the Toxic Substances Control Act of 1976, 15 U.S.C. Section 2601 et seq., and (e) Chapter 21E of the General Laws of Massachusetts. Tenant, at its sole cost and expense, shall comply with (i) Environmental Laws, and (ii) any rules, requirements and safety procedures of the Massachusetts Department of Environmental Protection, the City of Cambridge and any insurer of the Building or the Premises with respect to Tenant's use, storage and disposal of any Hazardous Materials.

17.3Hazardous Material Defined. As used herein, the term "**Hazardous Material**" means asbestos, oil or any hazardous, radioactive or toxic substance, material or waste or petroleum derivative which is or becomes regulated by any Environmental Law, including without limitation live organisms, viruses and fungi, medical waste and any so-called "biohazard" materials. The term "**Hazardous Material**" includes, without limitation, oil and/or any material or substance which is (i) designated as a "hazardous substance," "hazardous material," "oil," "hazardous waste" or toxic substance under any Environmental Law.

17.4Chemical Safety Program. Tenant shall establish and maintain a chemical safety program administered by a licensed, qualified individual in accordance with the requirements of any applicable governmental authority. Tenant shall be solely responsible for all costs incurred in connection with such chemical safety program, and Tenant shall provide Landlord with such documentation as Landlord may reasonably require evidencing Tenant's compliance with the requirements of (a) any applicable governmental authority with respect to such chemical safety program and (b) this Section. Tenant shall obtain and maintain during the Term any permit required by any such applicable governmental authority.

17.5Testing. If any Mortgagee or governmental authority requires testing to determine whether there has been any release of Hazardous Materials and such testing is required as a result of the acts or omissions of any of the Tenant Parties, then Tenant shall reimburse Landlord upon demand, as Additional Rent, for the reasonable costs thereof, together with interest at the Default Rate until paid in full. Tenant shall execute affidavits, certifications and the like, as may be reasonably requested by Landlord from time to time concerning Tenant's best knowledge and belief concerning the presence of Hazardous Materials in or on the Premises, the Building or the Property. In addition to the foregoing, if Landlord reasonably believes that any Hazardous Materials have been released on the Premises in violation of this Lease or any Legal Requirement, Landlord shall have the right to conduct appropriate tests of the Premises or any portion thereof to demonstrate that Hazardous Materials are present or that contamination has occurred due to the acts or omissions of any of the Tenant Parties.

At least five (5) Business Days prior to conducting any tests or taking action within the Premises, Landlord shall notify Tenant in writing with the details and basis of Landlord's belief that any Hazardous Materials have been released on the Premises in violation of this Lease or any Legal Requirement ("**Notice of Concern**"). If Tenant reasonably disagrees with Landlord that the information contained in the Notice of Concern supports the belief that any Hazardous Materials have been released on the Premises in violation of this Lease or any Legal Requirement, then Tenant and Landlord agree to discuss in good faith an appropriate course of action; provided, however, in the event the Notice of Concern is a result of any notice of a possible violation from a governmental authority, then Tenant shall have no right to disagree with Landlord's election to

conduct tests or take action within the Premises. If Landlord nevertheless conducts appropriate tests of the Premises or any potion thereof, then Tenant shall pay all reasonable costs of such tests if such tests reveal that Hazardous Materials exist at the Premises in violation of this Lease or any Legal Requirement. Further, Landlord shall have the right to cause a third party consultant retained by Landlord, at Landlord's expense (provided, however, that such costs shall be included in Operating Costs), to review, but not more than once in any calendar year, Tenant's lab operations, procedures and permits to ascertain whether or not Tenant is complying with law and adhering to standard industry practices. Tenant agrees to cooperate in good faith with any such review and to provide to such consultant any information requested by such consultant and reasonably required in order for such consultant to perform such review, but nothing contained herein shall require Tenant to provide proprietary or confidential information to such consultant.

17.6 Indemnity; Remediation.

(a) Tenant hereby covenants and agrees to indemnify, defend and hold the Landlord Parties harmless from and against any and all Claims against any of the Landlord Parties arising out of contamination of any part of the Property or other adjacent property, which contamination arises as a result of: (i) the presence of Hazardous Material in the Premises, the presence of which is caused by any act or omission of any of the Tenant Parties, or (ii) from a breach by Tenant of its obligations under this Section 17. This indemnification of the Landlord Parties by Tenant includes, without limitation, reasonable costs incurred in connection with any investigation of site conditions or any cleanup, remedial, removal or restoration work or any other response actions required by any federal, state or local governmental agency or political subdivision because of Hazardous Material present in the soil, soil vapor or ground water on or under or any indoor air in the Building based upon the circumstances identified in the first sentence of this Section 17.6. The indemnification and hold harmless obligations of Tenant under this Section 17.6 shall survive the expiration or any earlier termination of this Lease. Without limiting the foregoing, if the presence of any Hazardous Material in the Building or otherwise in the Property is caused or permitted by any of the Tenant Parties and results in any contamination of any part of the Property or any adjacent property, Tenant shall promptly take all actions at Tenant's sole cost and expense as are necessary to return the Property and/or the Building or any adjacent property to their condition as of the date of this Lease, provided that Tenant shall first obtain Landlord's written approval of such actions, which approval shall not be unreasonably withheld, conditioned or delayed so long as such actions, in Landlord's reasonable discretion, would not potentially have any adverse effect on the Property, and, in any event, Landlord shall not withhold its approval of any proposed actions which are required by applicable Environmental Laws. The provisions of this Section 17.6 shall survive the expiration or earlier termination of the Lease.

(b) Without limiting the obligations set forth in Section 17.6(a) above, if any Hazardous Material is in, on, under, at or about the Building or the Property as a result of the acts or omissions of any of the Tenant Parties and results in any contamination of any part of the Property or any adjacent property that is in violation of any applicable Environmental Law or that requires the performance of any response action pursuant to any Environmental Law, Tenant shall promptly take all actions at Tenant's sole cost and expense as are necessary to reduce such Hazardous Material to amounts below any applicable Reportable Quantity, any applicable Reportable Concentration and any other applicable standard set forth in any Environmental Law such that no further response actions are required; provided that Tenant shall first obtain Landlord's written approval of such actions, which approval shall not be unreasonably withheld, conditioned or delayed so long as such actions would not be reasonably expected to have an adverse effect on the market value or utility of the Property for the Permitted Uses, and in any event, Landlord shall not withhold its approval of any proposed actions which are required by applicable Environmental Laws (such approved actions, "**Tenant's Remediation**").

(c) In the event that Tenant fails to complete Tenant's Remediation prior to the end of the Term, then:

(i) until the completion of Tenant's Remediation (as evidenced by the certification of Tenant's Licensed Site Professional (as such term is defined by applicable Environmental Laws), who shall be reasonably acceptable to Landlord) (the "**Remediation Completion Date**"), Tenant shall pay to Landlord, with respect to the portion of the Premises which reasonably cannot be occupied by a new tenant until completion of Tenant's Remediation, (A) Additional Rent on account of Operating Costs and Taxes and (B) Base Rent in an amount equal to the greater of (1) the fair market rental value of such portion of the Premises (determined in substantial accordance with the process described in Section 1.2 above), and (2) Base Rent attributable to such portion of the Premises in effect immediately prior to the end of the Term; and

(ii) Tenant shall maintain responsibility for Tenant's Remediation and Tenant shall complete Tenant's Remediation as soon as reasonably practicable in accordance with Environmental Laws. If Tenant does not diligently pursue completion of Tenant's Remediation, Landlord shall have the right to either (A) assume control for overseeing Tenant's Remediation, in which event Tenant shall pay all reasonable costs and expenses of Tenant's Remediation (it being understood and agreed that all costs and expenses of Tenant's Remediation incurred pursuant to contracts entered into by Tenant shall be deemed reasonable) within thirty (30) days of demand therefor (which demand shall be made no more often than monthly), and Landlord shall be substituted as the party identified on any governmental filings as the party responsible for the performance of such Tenant's Remediation or (B) require Tenant to maintain responsibility for Tenant's Remediation, in which event Tenant shall complete Tenant's Remediation as soon as reasonably practicable in accordance with Environmental Laws, it being understood that Tenant's Remediation shall not contain any requirement that Tenant remediate any contamination to levels or standards more stringent than those associated with the Property's current office, research and development, and laboratory uses.

(d) The provisions of this Section 17.6 shall survive the expiration or earlier termination of this Lease.

17.7Disclosures. Prior to bringing any Hazardous Material into any part of the Property, Tenant shall deliver to Landlord the following information with respect thereto: (a) a description of handling, storage, use and disposal procedures; (b) all plans or disclosures and/or emergency response plans which Tenant has prepared, including without limitation Tenant's Spill Response Plan, and all plans which Tenant is required to supply to any governmental agency or authority pursuant to any Environmental Laws; (c) copies of all Required Permits relating thereto; and (d) other information reasonably requested by Landlord.

17.8Removal. Tenant shall be responsible, at its sole cost and expense, for Hazardous Material and other biohazard disposal services for the Premises. Such services shall be performed by contractors reasonably acceptable to Landlord and on a sufficient basis to ensure that the Premises are at all times kept neat, clean and free of Hazardous Materials and biohazards except in appropriate, specially marked containers reasonably approved by Landlord.

18. RULES AND REGULATIONS.

18.1Rules and Regulations. Tenant will faithfully observe and comply with the Rules and Regulations attached hereto as Exhibit 8 ("**Current Rules and Regulations**") and reasonable rules and regulations as may be promulgated, from time to time, with respect to the Building, the Property and construction within the Property (collectively, the "**Rules and Regulations**"). The Current Rules and Regulations consist of the Building Rules and Regulations attached hereto as Exhibit 8-1 and the Construction Rules and Regulations attached hereto as Exhibit 8-2. In the case of any conflict between the provisions of this Lease and the Rules and Regulations or any future rules and regulations, the provisions of this Lease shall control. Nothing contained in this Lease shall be construed to impose upon Landlord any duty or obligation to enforce the Rules and Regulations or the terms, covenants or conditions in any other lease as against any other tenant and Landlord shall not be liable to Tenant for violation of the same by any other tenant, its servants, employees, agents, contractors, visitors, invitees or licensees.

18.2Energy Conservation. Landlord may institute upon written notice to Tenant such policies, programs and measures as may be necessary, required, or expedient for the conservation and/or preservation of energy or energy services (collectively, the "**Conservation Program**"), provided however, that the Conservation Program does not, by reason of such policies, programs and measures, reduce the level of energy or energy services being provided to the Premises below the level of energy or energy services then being provided in comparable combination laboratory, research and development and office buildings in the vicinity of the Premises, or as may be necessary or required to comply with Legal Requirements or standards or the other provisions of this Lease. Upon receipt of such notice, Tenant shall comply with the Conservation Program.

18.3Recycling. Upon written notice, Landlord may establish policies, programs and measures for the recycling of paper, products, plastic, tin and other materials (a "**Recycling Program**"). Upon receipt of such notice, Tenant will comply with the Recycling Program at Tenant's sole cost and expense.

19. LAWS AND PERMITS.

19.1Legal Requirements. Tenant shall not cause or permit the Premises, or cause the Property or the Building to be used in any way that violates any Legal Requirement, order, permit, approval, variance, covenant or restrictions of record or any provisions of this Lease, interferes with the rights of tenants of the Building, or constitutes a nuisance or waste. Tenant shall obtain, maintain and pay for all permits and approvals needed for the operation of Tenant's business and/or Tenant's Penthouse Equipment, as soon as reasonably possible, and in any event shall not undertake any operations or use of Tenant's Penthouse Equipment unless all applicable permits and approvals are in place and shall, promptly take all actions necessary to comply with all Legal Requirements, including, without limitation, the Occupational Safety and Health Act, applicable to Tenant's use of the Premises, the Property or the Building. Tenant shall maintain in full force and effect all certifications or permissions required by any authority having jurisdiction to authorize, franchise or regulate Tenant's use of the Premises. Tenant shall be solely responsible for procuring and complying at all times with any and all necessary permits and approvals directly or indirectly relating or incident to: the conduct of its activities on the Premises; its scientific experimentation, transportation, storage, handling, use and disposal of any chemical or radioactive or bacteriological or pathological substances or organisms or other hazardous wastes or environmentally dangerous substances or materials or medical waste or animals or laboratory specimens. Within ten (10) days of a request by Landlord, which request shall be made not more than once during each period of twelve (12) consecutive months during the Term hereof, unless otherwise requested by any mortgagee of Landlord or unless Landlord reasonably suspects that Tenant has violated the provisions of this Section 19.1, Tenant shall furnish Landlord with copies of all such permits and approvals that Tenant possesses or has obtained together with a certificate certifying that such permits are all of the permits that Tenant possesses or has obtained with respect to the Premises. Tenant shall promptly give written notice to Landlord of any warnings or violations relative to the above received from any federal, state or municipal agency or by any court of law and shall promptly cure the conditions causing any such violations. Tenant shall not be deemed to be in default of its obligations under the preceding sentence to promptly cure any condition causing any such violation in the event that, in lieu of such cure, Tenant shall contest the validity of such violation by appellate or other proceedings permitted under applicable law, provided that: (i) any such contest is made reasonably and in good faith, (ii) Tenant makes provisions, including, without limitation, posting bond(s) or giving other security, reasonably acceptable to Landlord to protect Landlord, the Building and the Property from any liability, costs, damages or expenses arising in connection with such alleged violation and failure to cure, (iii) Tenant shall agree to indemnify, defend (with counsel reasonably acceptable to Landlord) and hold Landlord harmless from and against any and all liability, costs, damages, or expenses arising in connection with such condition and/or violation, (iv) Tenant shall promptly cure any violation in the event that its appeal of such violation is overruled or rejected, and (v) Tenant's decision to delay such cure shall not, in Landlord's good faith determination, be likely to result in any actual or threatened bodily injury, property damage, or any civil or criminal liability to Landlord, any tenant or occupant of the Building or the Property, or any other person or entity. Nothing contained in this Section 19.1 shall be construed to expand the uses permitted hereunder beyond the Permitted Uses. Landlord shall comply with any Legal Requirements and with any direction of any public office or officer relating to the maintenance or operation of the structural elements of the Building and the Common Areas, and the costs so incurred by Landlord shall be included in Operating Costs in accordance with the provisions of Section 5.2.

20. DEFAULT

20.1Events of Default. The occurrence of any one or more of the following events shall constitute an "**Event of Default**" hereunder by Tenant:

(a) If Tenant fails to make any payment of Rent or any other payment required hereunder, as and when due, and such failure shall continue for a period of three (3) business days after written notice thereof from Landlord to Tenant; provided, however, an Event of Default shall occur hereunder without any obligation of Landlord to give any notice if (i) Tenant fails to make any payment within three (3) business days after the due date therefor, and (ii) Landlord has given Tenant written notice under this Section 20.1(a) on more than one (1) occasion during the twelve (12) month interval preceding such failure by Tenant;

(b) If Tenant shall abandon the Premises (whether or not the keys shall have been surrendered or the Rent shall have been paid);

(c) If Tenant shall fail to execute and deliver to Landlord an estoppel certificate pursuant to Section 16 above or a subordination and attornment agreement pursuant to Section 22 below, within the timeframes set forth therein, and such failure shall continue for a period of five (5) business days after written notice thereof from Landlord to Tenant;

(d) If Tenant shall fail to maintain any insurance required hereunder;

(e) If Tenant shall fail to restore the Security Deposit to its original amount or deliver a replacement Letter of Credit as required under Section 7 above;

(f) If Tenant causes or suffers any release of Hazardous Materials in or near the Property;

(g) If Tenant shall make a Transfer in violation of the provisions of Section 13 above, or if any event shall occur or any contingency shall arise whereby this Lease, or the term and estate thereby created, would (by operation of law or otherwise) devolve upon or pass to any person, firm or corporation other than Tenant, except as expressly permitted under Section 13 hereof;

(h) If Tenant shall fail to perform its obligations under Section 3 hereof and such failure continues for more than thirty (30) days after notice thereof from Landlord;

(i) The failure by Tenant to observe or perform any of the covenants or provisions of this Lease to be observed or performed by Tenant, other than as specified above, and such failure continues for more than thirty (30) days after notice thereof from Landlord; provided, further, that if the nature of Tenant's default is such that more than thirty (30) days are reasonably required for its cure, then Tenant shall not be deemed to be in default if Tenant shall commence such cure within said thirty (30) day period and thereafter diligently prosecute such cure to completion, which completion shall occur not later than ninety (90) days from the date of such notice from Landlord;

(j) Tenant shall be involved in financial difficulties as evidenced by an admission in writing by Tenant of Tenant's inability to pay its debts generally as they become due, or by the making or offering to make a composition of its debts with its creditors;

(k) Tenant shall make an assignment or trust mortgage, or other conveyance or transfer of like nature, of all or a substantial part of its property for the benefit of its creditors,

(l) an attachment on mesne process, on execution or otherwise, or other legal process shall issue against Tenant or its property and a sale of any of its assets shall be held thereunder;

(m) any judgment, attachment or the like in excess of $100,000 shall be entered, recorded or filed against Tenant in any court, registry, etc. and Tenant shall fail to pay such judgment within thirty (30) days after the judgment shall have become final beyond appeal or to discharge or secure by surety bond such lien, attachment, etc. within thirty (30) days of such entry, recording or filing, as the case may be;

(n) the leasehold hereby created shall be taken on execution or by other process of law and shall not be revested in Tenant within thirty (30) days thereafter;

(o) a receiver, sequesterer, trustee or similar officer shall be appointed by a court of competent jurisdiction to take charge of all or any part of Tenant's Property and such appointment shall not be vacated within thirty (30) days; or

(p) any proceeding shall be instituted by or against Tenant pursuant to any of the provisions of any Act of Congress or State law relating to bankruptcy, reorganizations, arrangements, compositions or other relief from creditors, and, in the case of any proceeding instituted against it, if Tenant shall fail to have such proceedings dismissed within thirty (30) days or if Tenant is adjudged bankrupt or insolvent as a result of any such proceeding;

Wherever "Tenant " is used in subsections (i), (j), (k), (l), (n) or (o) of this Section 20.1, it shall be deemed to include any parent entity of Tenant and any guarantor of any of Tenant's obligations under this Lease.

20.2Remedies. Upon an Event of Default, Landlord may, by notice to Tenant, elect to terminate this Lease; and thereupon (and without prejudice to any remedies which might otherwise be available for arrears of Rent or preceding breach of covenant or agreement and without prejudice to Tenant's liability for damages as hereinafter stated), upon the giving of such notice, this Lease shall terminate as of the date specified therein as though that were the Expiration Date. Upon such termination, Landlord shall have the right to utilize the Security Deposit or draw down the entire Letter of Credit, as applicable, and apply the proceeds thereof to its damages hereunder. Without being taken or deemed to be guilty of any manner of trespass or conversion, and without being liable to indictment, prosecution or damages therefor, Landlord may, by lawful process, enter into and upon the Premises (or any part thereof in the name of the whole); repossess the same, as of its former estate; and expel Tenant and those claiming under Tenant. The words "re- entry" and "re-enter" as used in this Lease are not restricted to their technical legal meanings.

20.3 Damages - Termination.

(a) Upon the termination of this Lease under the provisions of this Section 20, Tenant shall pay to Landlord Rent up to the time of such termination, shall continue to be liable for any preceding breach of covenant, and in addition, shall pay to Landlord as damages, at the election of Landlord, either:

(i) the amount (discounted to present value at the rate of five percent (5%) per annum) by which, at the time of the termination of this Lease (or at any time thereafter if Landlord shall have initially elected damages under Section 20.3(a)(ii) below), (x) the aggregate of Rent projected over the period commencing with such termination and ending on the Expiration Date, exceeds (y) the aggregate projected rental value of the Premises for such period, taking into account a reasonable time period during which the Premises shall be unoccupied, plus all Reletting Costs (hereinafter defined); or

(ii) amounts equal to Rent which would have been payable by Tenant had this Lease not been so terminated, payable upon the due dates therefor specified herein following such termination and until the Expiration Date, *provided*, *however*, if Landlord shall re- let the Premises during such period, that Landlord shall credit Tenant with the net rents received by Landlord from such re-letting, such net rents to be determined by first deducting from the gross rents as and when received by Landlord from such re-letting the expenses incurred or paid by Landlord in terminating this Lease, as well as the expenses of re-letting, including altering and preparing the Premises for new tenants, brokers' commissions, and all other similar and dissimilar expenses properly chargeable against the Premises and the rental therefrom (collectively, "**Reletting Costs**"), it being understood that any such re-letting may be for a period equal to or shorter or longer than the remaining Term; and *provided*, *further*, that (x) in no event shall Tenant be entitled to receive any excess of such net rents over the sums payable by Tenant to Landlord hereunder and (y) in no event shall Tenant be entitled in any suit for the collection of damages pursuant to this Section 20.3(a)(ii) to a credit in respect of any net rents from a re-letting except to the extent that such net rents are actually received by Landlord prior to the commencement of such suit. If the Premises or any part thereof should be re-let in combination with other space, then proper apportionment on a square foot area basis shall be made of the rent received from such re- letting and of the expenses of re-letting.

(b) In calculating the amount due under Section 20.3(a)(i), above, there shall be included, in addition to the Base Rent, all other considerations agreed to be paid or performed by Tenant, including without limitation Tenant's Share of Operating Costs and Taxes, on the assumption that all such amounts and considerations would have increased at the rate of five percent (5%) per annum for the balance of the full term hereby granted.

(c) Suit or suits for the recovery of such damages, or any installments thereof, may be brought by Landlord from time to time at its election, and nothing contained herein shall be deemed to require Landlord to postpone suit until the date when the Term would have expired if it had not been terminated hereunder.

(d) Nothing herein contained shall be construed as limiting or precluding the recovery by Landlord against Tenant of any sums or damages to which, in addition to the damages particularly provided above, Landlord may lawfully be entitled by reason of any Event of Default hereunder.

(e) In lieu of any other damages or indemnity and in lieu of full recovery by Landlord of all sums payable under all the foregoing provisions of this Section 20.3, Landlord may, by written notice to Tenant, at any time after this Lease is terminated under any of the provisions herein contained or is otherwise terminated for breach of any obligation of Tenant and before such full recovery, elect to recover, and Tenant shall thereupon pay, as liquidated damages, an amount equal to the aggregate of (x) an amount equal to the lesser of (1) Rent accrued under this Lease in the twelve (12) months immediately prior to such termination, or (2) Rent payable during the remaining months of the Term if this Lease had not been terminated, plus (y) the amount of Rent accrued and unpaid at the time of termination, less (z) the amount of any recovery by Landlord under the foregoing provisions of this Section 20.3 up to the time of payment of such liquidated damages.

20.4Landlord's Self-Help; Fees and Expenses. If Tenant shall default in the performance of any covenant on Tenant's part to be performed in this Lease contained, including without limitation the obligation to maintain the Premises in the required condition pursuant to Section 10.1 above, Landlord may, upon reasonable advance notice, except that no notice shall be required in an emergency, immediately, or at any time thereafter, perform the same for the account of Tenant. Tenant shall pay to Landlord upon demand therefor any costs incurred by Landlord in connection therewith, together with interest at the Default Rate until paid in full. In addition, Tenant shall pay all of Landlord's costs and expenses, including without limitation reasonable attorneys' fees, incurred (i) in enforcing any obligation of Tenant under this Lease or (ii) as a result of Landlord or any of the Landlord Parties, without its fault, being made party to any litigation pending by or against any of the Tenant Parties.

20.5Waiver of Redemption, Statutory Notice and Grace Periods. Tenant does hereby waive and surrender all rights and privileges which it might have under or by reason of any present or future Legal Requirements to redeem the Premises or to have a continuance of this Lease for the Term hereby demised after being dispossessed or ejected therefrom by process of law or under the terms of this Lease or after the termination of this Lease as herein provided. Except to the extent prohibited by Legal Requirements, any statutory notice and grace periods provided to Tenant by law are hereby expressly waived by Tenant.

20.6Landlord's Remedies Not Exclusive. The specified remedies to which Landlord may resort hereunder are cumulative and are not intended to be exclusive of any remedies or means of redress to which Landlord may at any time be lawfully entitled, and Landlord may invoke any remedy (including the remedy of specific performance) allowed at law or in equity as if specific remedies were not herein provided for.

20.7No Waiver. Landlord's failure to seek redress for violation, or to insist upon the strict performance, of any covenant or condition of this Lease, or any of the Rules and Regulations promulgated hereunder, shall not prevent a subsequent act, which would have originally constituted a violation, from having all the force and effect of an original violation. The receipt by

Landlord of Rent with knowledge of the breach of any covenant of this Lease shall not be deemed a waiver of such breach. The failure of Landlord to enforce any of such Rules and Regulations against Tenant and/or any other tenant in the Building shall not be deemed a waiver of any such Rules and Regulations. No provisions of this Lease shall be deemed to have been waived by either party unless such waiver be in writing signed by such party. No payment by Tenant or receipt by Landlord of a lesser amount than the Rent herein stipulated shall be deemed to be other than on account of the stipulated Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or pursue any other remedy in this Lease provided.

20.8Restrictions on Tenant's Rights. During the continuation of any Event of Default, (a) Landlord shall not be obligated to provide Tenant with any notice pursuant to Sections 2.3 and 2.4 above; and (b) Tenant shall not have the right to make, nor to request Landlord's consent or approval with respect to, any Alterations or Transfers.

20.9Landlord Default. Notwithstanding anything to the contrary contained in the Lease, Landlord shall in no event be in default in the performance of any of Landlord's obligations under this Lease unless Landlord shall have failed to perform such obligations within thirty (30) days (or such additional time as is reasonably required to correct any such default, provided Landlord commences cure within 30 days) after notice by Tenant to Landlord properly specifying wherein Landlord has failed to perform any such obligation. Except as expressly set forth in this Lease, Tenant shall not have the right to terminate or cancel this Lease or to withhold rent or to set-off or deduct any claim or damages against rent as a result of any default by Landlord or breach by Landlord of its covenants or any warranties or promises hereunder, except in the case of a wrongful eviction of Tenant from the Premises (constructive or actual) by Landlord, and then only if the same continues after notice to Landlord thereof and an opportunity for Landlord to cure the same as set forth above. In addition, Tenant shall not assert any right to deduct the cost of repairs or any monetary claim against Landlord from rent thereafter due and payable under this Lease.

21. SURRENDER; ABANDONED PROPERTY; HOLD-OVER

21.1 Surrender

(a) Upon the expiration or earlier termination of the Term, Tenant shall (i) peaceably quit and surrender to Landlord the Premises (including, without limitation, all fixed lab benches, fume hoods, electric, plumbing, heating and sprinkling systems, fixtures and outlets, vaults, paneling, molding, shelving, radiator enclosures, cork, rubber, linoleum and composition floors, ventilating, silencing, air conditioning and cooling equipment therein, Landlord's Work, and all other furniture, fixtures, and equipment that was either provided by Landlord or paid for in whole or in part by any allowance provided to Tenant by Landlord under this Lease) broom clean, in good order, repair and condition excepting only ordinary wear and tear and damage by fire or other insured Casualty; (ii) remove all of Tenant's Property, all autoclaves and cage washers and, at Landlord's election, any Alterations made by Tenant (in accordance with Section 11.1); and (iii) repair any damages to the Premises or the Building caused by the installation or removal of Tenant's Property and/or such Alterations. Tenant's obligations under this Section 21.1(a) shall survive the expiration or earlier termination of this Lease.

(b) Prior to the expiration of this Lease (or within thirty (30) days after any earlier termination), Tenant shall clean and otherwise decommission all interior surfaces (including floors, walls, ceilings, and counters), piping, supply lines, waste lines, acid neutralization systems and plumbing in and/or exclusively serving the Premises, and all exhaust or other ductwork in and/or exclusively serving the Premises, in each case which has carried or released or been contacted by any Hazardous Materials or other chemical or biological materials used in the operation of the Premises, and shall otherwise clean the Premises so as to permit the Surrender Plan (defined below) to be issued. At least thirty (30) days prior to the expiration of the Term (or, if applicable, within five (5) business days after any earlier termination of this Lease), Tenant shall deliver to Landlord a reasonably detailed narrative description of the actions proposed (or required by any Legal Requirements) to be taken by Tenant in order to render the Premises (including any Alterations permitted or required by Landlord to remain therein) free of Hazardous Materials and otherwise released for unrestricted use and occupancy including without limitation causing the Premises to be decommissioned in accordance with the regulations of the U.S. Nuclear Regulatory Commission and/or the Massachusetts Department of Public health (the "**MDPH**") for the control of radiation, and cause the Premises to be released for unrestricted use by the Radiation Control Program of the MDPH (the "**Surrender Plan**"). The Surrender Plan (i) shall be accompanied by a current list of (A) all Required Permits held by or on behalf of any Tenant Party with respect to Hazardous Materials in, on, under, at or about the Premises, and (B) Tenant's Hazardous Materials, and (ii) shall be subject to the review and approval of Landlord's environmental consultant. In connection with review and approval of the Surrender Plan, upon request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non- proprietary information concerning the use of and operations within the Premises as Landlord shall request. On or before the expiration of the Term (or within thirty (30) days after any earlier termination of this Lease, during which period Tenant's use and occupancy of the Premises shall be governed by Section 21.3 below), Tenant shall (i) perform or cause to be performed all actions described in the approved Surrender Plan, and (ii) deliver to Landlord a certification from a third party certified industrial hygienist reasonably acceptable to Landlord certifying that the Premises do not contain any Hazardous Materials and evidence that the approved Surrender Plan shall have been satisfactorily completed by a contractor acceptable to Landlord, and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the expiration of the Term (or, if applicable, the date which is thirty (30) days after any earlier termination of this Lease), free of Hazardous Materials and otherwise available for unrestricted use and occupancy as aforesaid. Landlord shall have the unrestricted right to deliver the Surrender Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties. Such third parties and the Landlord Parties shall be entitled to rely on the Surrender Report. If Tenant shall fail to prepare or submit a Surrender Plan approved by Landlord, or if Tenant shall fail to complete the approved Surrender Plan, or if such Surrender Plan, whether or not approved by Landlord, shall fail to adequately address the use of Hazardous Materials by any of the Tenant Parties in, on, at, under or about the Premises, Landlord shall have the right to take any such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Property are surrendered in the condition required hereunder, the cost of which actions shall be reimbursed by Tenant as Additional Rent upon demand. Tenant's obligations under this Section 21.1(b) shall survive the expiration or earlier termination of the Term.

(c) No act or thing done by Landlord during the Term shall be deemed an acceptance of a surrender of the Premises, and no agreement to accept such surrender shall be valid, unless in writing signed by Landlord. Unless otherwise agreed by the parties in writing, no employee of Landlord or of Landlord's agents shall have any power to accept the keys of the Premises prior to the expiration or earlier termination of this Lease. The delivery of keys to any employee of Landlord or of Landlord's agents shall not operate as a termination of this Lease or a surrender of the Premises.

(d) Notwithstanding anything to the contrary contained herein, Tenant shall, at its sole cost and expense, remove from the Premises, prior to the end of the Term, any item installed by or for Tenant and which, pursuant to Legal Requirements, must be removed therefrom before the Premises may be used by a subsequent tenant.

21.2Abandoned Property. After the expiration or earlier termination hereof, if Tenant fails to remove any property from the Building or the Premises which Tenant is obligated by the terms of this Lease to remove within five (5) business days after written notice from Landlord, such property (the "**Abandoned Property**") shall be conclusively deemed to have been abandoned, and may either be retained by Landlord as its property or sold or otherwise disposed of in such manner as Landlord may see fit. If any item of Abandoned Property shall be sold, Tenant hereby agrees that Landlord may receive and retain the proceeds of such sale and apply the same, at its option, to the expenses of the sale, the cost of moving and storage, any damages to which Landlord may be entitled under Section 20 hereof or pursuant to law, and to any arrears of Rent.

21.3Holdover. If any of the Tenant Parties holds over (which term shall include, without limitation, the failure of Tenant or any Tenant Party to perform all of its obligations under Section 21.1 above) after the end of the Term, Tenant shall be deemed a tenant-at-sufferance subject to the provisions of this Lease. Whether or not Landlord has previously accepted payments of Rent from Tenant:

(i) Tenant shall pay Base Rent at the Hold Over Percentage, as hereinafter defined, of the highest rate of Base Rent payable during the Term,

(ii) Tenant shall continue to pay to Landlord all Additional Rent, and

(iii)in the event such hold over extends beyond thirty (30) days after the end of the Term, Tenant shall be liable for all damages, including without limitation lost business and consequential damages, incurred by Landlord as a result of such holding over, Tenant hereby acknowledging that Landlord may need the Premises after the end of the Term for other tenants and that the damages which Landlord may suffer as the result of Tenant's holding over cannot be determined as of the Execution Date. Nothing contained herein shall grant Tenant the right to holdover after the expiration or earlier termination of the Term. The "Hold Over Percentage" shall be 150% for the first thirty (30) days of such holdover, and 200% for any period of hold over after the first thirty (30) days. Nothing contained herein shall grant Tenant the right to holdover after the expiration or earlier termination of the Term.

21.4Warranties. Tenant hereby assigns to Landlord any warranties in effect on the last day of the Term with respect to any fixtures and Alterations installed in the Premises. Tenant shall provide Landlord with copies of any such warranties prior to the expiration of the Term (or, if the Lease is earlier terminated, within five (5) days thereafter).

22. MORTGAGEE RIGHTS

22.1Subordination. Tenant's rights and interests under this Lease shall be (i) subject and subordinate to any ground lease, overleases, mortgage, deed of trust, or similar instrument covering the Premises, the Building and/or the Land and to all advances, modifications, renewals, replacements, and extensions thereof (each of the foregoing, a "**Mortgage**"), or (ii) if any Mortgagee elects, prior to the lien of any present or future Mortgage. Tenant further shall attorn to and recognize any successor landlord, whether through foreclosure or otherwise, as if the successor landlord were the originally named landlord. The provisions of this Section 22.1 shall be self-operative and no further instrument shall be required to effect such subordination or attornment; however, Tenant agrees to execute, acknowledge and deliver such instruments, confirming such subordination and attornment in such form as shall be requested by any such holder within fifteen (15) days of request therefor. Landlord agrees to use reasonable efforts to obtain a subordination, non-disturbance and attornment agreement ("**SNDA**") on the standard form of SNDA then being used by the holder of the Mortgage in question, with such commercially reasonable modifications as may be requested by Tenant. Landlord represents to Tenant that, as of the Execution Date, there are no mortgages affecting the Building or the Land.

22.2Notices. Tenant shall give each Mortgagee the same notices given to Landlord concurrently with the notice to Landlord, and each Mortgagee shall have a reasonable opportunity thereafter to cure a Landlord default, and Mortgagee's curing of any of Landlord's default shall be treated as performance by Landlord.

22.3Mortgagee Consent. Tenant acknowledges that, where applicable, any consent or approval hereafter given by Landlord may be subject to the further consent or approval of a Mortgagee; and the failure or refusal of such Mortgagee to give such consent or approval shall, notwithstanding anything to the contrary in this Lease contained, constitute reasonable justification for Landlord's withholding its consent or approval.

22.4Mortgagee Liability. Tenant acknowledges and agrees that if any Mortgage shall be foreclosed, (a) the liability of the Mortgagee and its successors and assigns shall exist only so long as such Mortgagee or purchaser is the owner of the Premises, and such liability shall not continue or survive after further transfer of ownership; and (b) such Mortgagee and its successors or assigns shall not be (i) liable for any act or omission of any prior lessor under this Lease; (ii) liable for the performance of Landlord's covenants pursuant to the provisions of this Lease which arise and accrue prior to such entity succeeding to the interest of Landlord under this Lease or acquiring such right to possession; (iii) subject to any offsets or defense which Tenant may have at any time against Landlord; (iv) bound by any base rent or other sum which Tenant may have paid previously for more than one (1) month; or (v) liable for the performance of any covenant of Landlord under this Lease which is capable of performance only by the original Landlord.

23. QUIET ENJOYMENT.

Landlord covenants that so long as Tenant keeps and performs each and every covenant, agreement, term, provision and condition herein contained on the part and on behalf of Tenant to be kept and performed, Tenant shall peaceably and quietly hold, occupy and enjoy the Premises during the Term from and against the claims of all persons lawfully claiming by, through or under Landlord subject, nevertheless, to the covenants, agreements, terms, provisions and conditions of this Lease, any matters of record or of which Tenant has knowledge and to any Mortgage to which this Lease is subject and subordinate, as hereinabove set forth.

24. NOTICES.

Any notice, consent, request, bill, demand or statement hereunder (each, a "**Notice**") by either party to the other party shall be in writing and shall be deemed to have been duly given when either delivered by hand or by nationally recognized overnight courier (in either case with evidence of delivery or refusal thereof) addressed as follows:

If to Landlord:	HCP/King 101 CPD LLC c/o King Street Properties 800 Boylston Street, Suite 1570 Boston, MA 02199 Attn: Stephen D. Lynch
With a copy to:	Goulston & Storrs PC 400 Atlantic Avenue Boston, MA 02110 Attention: King Street
if to Tenant:	Seres Therapeutics, Inc. 200 Sidney Street, 4th Floor Cambridge, Massachusetts 02139
With a copy to:	Seres Therapeutics, Inc. 200 Sidney Street, 4th Floor Cambridge, Massachusetts 02139 Attn: Chief Financial Officer

Notwithstanding the foregoing, any notice from Landlord to Tenant regarding ordinary business operations (e.g., exercise of a right of access to the Premises, maintenance activities, invoices, etc.) may also be given by written notice delivered by email to those parties listed in Section 2.4. Either party may at any time change the address or specify an additional address for such Notices by delivering or mailing, as aforesaid, to the other party a notice stating the change and setting forth the changed or additional address, provided such changed or additional address is within the United States. Notices shall be effective upon the date of receipt or refusal thereof.

25. MISCELLANEOUS

25.1Separability. If any provision of this Lease or portion of such provision or the application thereof to any person or circumstance is for any reason held invalid or unenforceable, the remainder of this Lease (or the remainder of such provision) and the application thereof to other persons or circumstances shall not be affected thereby.

25.2Captions. The captions are inserted only as a matter of convenience and for reference, and in no way define, limit or describe the scope of this Lease nor the intent of any provisions thereof.

25.3Broker. Tenant and Landlord each warrants and represents that it has dealt with no broker in connection with the consummation of this Lease other than Newmark (the "**Broker**"). Tenant and Landlord each agrees to defend, indemnify and save the other harmless from and against any Claims arising in breach of the representation and warranty set forth in the immediately preceding sentence. Landlord shall be solely responsible for the payment of any brokerage commissions to the Broker pursuant to a separate agreement between Landlord and the Broker.

25.4Entire Agreement. This Lease, Lease Summary Sheet and Exhibits 1-12 attached hereto and incorporated herein contain the entire and only agreement between the parties and any and all statements and representations, written and oral, including previous correspondence and agreements between the parties hereto, are merged herein. Tenant acknowledges that all representations and statements upon which it relied in executing this Lease are contained herein and that Tenant in no way relied upon any other statements or representations, written or oral. This Lease may not be modified orally or in any manner other than by written agreement signed by the parties hereto.

25.5Governing Law. This Lease is made pursuant to, and shall be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts and any applicable local municipal rules, regulations, by-laws, ordinances and the like.

25.6Representation of Authority. By his or her execution hereof, each of the signatories on behalf of the respective parties hereby warrants and represents to the other that he or she is duly authorized to execute this Lease on behalf of such party. Upon Landlord's request, Tenant shall provide Landlord with evidence that any requisite resolution, corporate authority and any other necessary consents have been duly adopted and obtained.

25.7Expenses Incurred by Landlord Upon Tenant Requests. Tenant shall, upon demand, reimburse Landlord for all reasonable expenses, including, without limitation, legal fees, incurred by Landlord in connection with all requests by Tenant for consents, approvals or execution of collateral documentation related to this Lease, including, without limitation, costs incurred by Landlord in the review and approval of Tenant's plans and specifications in connection with proposed Alterations to be made by Tenant to the Premises or in connection with requests by Tenant for Landlord's consent to make a Transfer. Such costs shall be deemed to be Additional Rent under this Lease.

25.8Survival. Without limiting any other obligation of Tenant which may survive the expiration or prior termination of the Term, all obligations on the part of Tenant to indemnify, defend, or hold Landlord harmless, as set forth in this Lease shall survive the expiration or prior termination of the Term.

25.9Limitation of Liability. Tenant shall neither assert nor seek to enforce any claim against Landlord or any of the Landlord Parties, or the assets of any of the Landlord Parties, for breach of this Lease or otherwise, other than against Landlord's interest in the Building and in the uncollected rents, issues and profits thereof, and Tenant agrees to look solely to such interest for the satisfaction of any liability of Landlord under this Lease. This Section 25.9 shall not limit any right that Tenant might otherwise have to obtain injunctive relief against Landlord. **Landlord and Tenant specifically agree that in no event shall any officer, director, trustee, employee or representative of Landlord or any of the other Landlord Parties ever be personally liable for any obligation under this Lease, nor shall Landlord or any of the other Landlord Parties be liable for consequential or incidental damages or for lost profits whatsoever in connection with this Lease.**

25.10Binding Effect. The covenants, agreements, terms, provisions and conditions of this Lease shall bind and benefit the successors and assigns of the parties hereto with the same effect as if mentioned in each instance where a party hereto is named or referred to, except that no violation of the provisions of Section 13 hereof shall operate to vest any rights in any successor or assignee of Tenant. This Lease may be signed in counterparts and a facsimile or electronic signature on this Lease shall be equivalent to, and have the same force and effect as, an original signature.

25.11Landlord Obligations upon Transfer. Upon any sale, transfer or other disposition of the Building, Landlord shall be entirely freed and relieved from the performance and observance thereafter of all covenants and obligations hereunder on the part of Landlord to be performed and observed, it being understood and agreed in such event (and it shall be deemed and construed as a covenant running with the land) that the person succeeding to Landlord's ownership of said reversionary interest shall thereupon and thereafter assume, and perform and observe, any and all of such covenants and obligations of Landlord, except as otherwise agreed in writing.

25.12No Grant of Interest. Tenant shall not grant any interest whatsoever in any fixtures within the Premises or any item paid in whole or in part by Landlord's Contribution or by Landlord.

25.13Financial Information. Tenant shall deliver to Landlord, within thirty (30) days after Landlord's reasonable request, Tenant's most recently completed balance sheet and related statements of income, shareholder's equity and cash flows statements (audited if available) reviewed by an independent certified public accountant and certified by an officer of Tenant as being true and correct in all material respects. Any such financial information may be relied upon by any actual or potential lessor, purchaser, or mortgagee of the Property or any portion thereof.

25.14OFAC Certificate and Indemnity. Executive Order No. 13224 on Terrorist Financing, effective September 24, 2001 (the "**Executive Order**"), and the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (Public Law 10756, the "**Patriot Act**") prohibit certain property transfers. Tenant hereby represents and warrants to Landlord (which representations and warranties shall be deemed to be continuing and re-made at all times during the Term) that neither Tenant nor any stockholder, manager, beneficiary, partner, or principal of Tenant is subject to the Executive Order, that none of them is listed on the United States Department of the Treasury Office of Foreign Assets Control ("OFAC") list of "Specially Designated Nationals and Blocked Persons" as modified from time to time, and that none of them is otherwise subject to the provisions of the Executive Order or the Patriot Act. The most current list of "**Specially Designated Nationals and Blocked Persons**" can be found at http://www.treas.gov/offices/eotffc/ofac/sdn/index.html. Tenant shall from time to time, within ten days after request by Landlord, deliver to Landlord any certification or other evidence requested from time to time by Landlord in its reasonable discretion, confirming Tenant's compliance with these provisions. No assignment or subletting shall be effective unless and until the assignee or subtenant thereunder delivers to Landlord written confirmation of such party's compliance with the provisions of this subsection, in form and content satisfactory to Landlord. If for any reason the representations and warranties set forth in this subsection, or any certificate or other evidence of compliance delivered to Landlord hereunder, is untrue in any respect when made or delivered, or thereafter becomes untrue in any respect, then an Event of Default hereunder shall be deemed to occur immediately, and there shall be no opportunity to cure. Tenant shall indemnify, defend with counsel reasonably acceptable to Landlord, and hold Landlord harmless from and against, any and all liabilities, losses claims, damages, penalties, fines, and costs (including attorneys' fees and costs) arising from or related to the breach of any of the foregoing representations, warranties, and duties of Tenant. The provisions of this subsection shall survive the expiration or earlier termination of this Lease for the longest period permitted by law.

25.15Confidentiality. Tenant acknowledges and agrees that the terms of this Lease are confidential. Disclosure of the terms hereof could adversely affect the ability of Landlord to negotiate other leases with respect to the Building and may impair Landlord's relationship with other tenants of the Building. Tenant agrees that it and its partners, officers, directors, employees, brokers, and attorneys, if any, shall not disclose the terms and conditions of this Lease to any other person or entity without the prior written consent of Landlord which may be given or withheld by Landlord, in Landlord's sole discretion, except as required for financial disclosures or securities filings, as required by the order of any court or public body with authority over Tenant, or in connection with any litigation between Landlord and Tenant with respect to this Lease. It is understood and agreed that damages alone would be an inadequate remedy for the breach of this provision by Tenant, and Landlord shall also have the right to seek specific performance of this provision and to seek injunctive relief to prevent its breach or continued breach.

25.16Force Majeure. Other than for Tenant's obligations under this Lease that can be performed by the payment of money (e.g., payment of Rent and maintenance of insurance), whenever a period of time is herein prescribed for action to be taken by either party hereto, such party shall not be liable or responsible for, and there shall be excluded from the computation of any such period of time, any delays due to strikes, riots, acts of God, shortages of labor or materials, war, acts of terrorism, governmental laws, regulations, or restrictions, national or regional

emergency, or a pandemic, epidemic or other public health emergency or exigency, or any other causes of any kind whatsoever which are beyond the control of such party (collectively "**Force Majeure**"). In no event shall financial inability of a party be deemed to be Force Majeure.

25.17Jury Trial Waiver. Landlord and Tenant hereby waive trial by jury in any action, proceeding or counterclaim brought by either party against the other on any matters in any way arising out of or connected with this Lease, the relationship of Landlord and Tenant, Tenant's use or occupancy of the premises, or the enforcement of any remedy under any statute, emergency or otherwise**.**

25.18LEED Guidelines. Tenant acknowledges and agrees the Building shall be LEED Certified, and Landlord has provided Tenant with a copy of the LEED Guidelines attached hereto as Exhibit 10, and Tenant shall comply with such reasonable rules and regulations as Landlord may require in order to maintain such status.

26. RIGHT OF FIRST OFFER.

26.1Grant of Option. Subject to the provisions of this Section 26, from and after the initial leasing by Landlord of the ROFO Premises to one or more tenants, Tenant shall have a one- time right of first offer (the "**ROFO**") to lease the ROFO Premises at the time that the ROFO Premises become available for lease, so long as the ROFO Conditions, (which ROFO Conditions Landlord may waive, at its election, by written notice to Tenant at any time), are satisfied both at the time that Landlord is required to give an Offer, and as of the commencement date of the term of the ROFO Premises (such dates being hereinafter collectively referred to as the "**ROFO Conditions Dates**").

26.2Definition of ROFO Premises. The "**ROFO Premises**" shall be defined as any space on the second (2nd) floor of the Building and the western portion of the third (3rd) floor of the Building as initially demised by Landlord, when such area becomes available for lease, during the Term of this Lease. For the purposes of this Section 26.2, the ROFO Premises shall be deemed to be "**available for lease**" if, during the Term of this Lease, Landlord, in its sole judgment, determines that such area will become available for leasing to Tenant (i.e. when Landlord determines that the then current tenant of such ROFO Premises will vacate such ROFO Premises, and all Superior Rights with respect to such ROFO Premises have either lapsed unexercised or have been irrevocably waived by the current tenant of such ROFO Premises, and when Landlord intends to offer such area for lease). "**Superior Rights**" shall be defined as: (i) the right of the existing tenant or occupant of the ROFO Premises to extend or renew the term of its lease of the ROFO Premises, or the applicable portion thereof, (ii) the rights of any existing tenant or occupant whose lease or occupancy agreement was executed prior to the Execution Date of this Lease to lease the ROFO Premises, and (iii) the right of Landlord to enter into an agreement with any existing tenant or occupant of the ROFO Premises, or the applicable portion thereof, renewing or extending such lease or occupancy agreement. Nothing set forth in this Section 26 shall be construed to limit Landlord's right to lease space in the Building to affiliates of Landlord, or to keep space in the Building vacant if Landlord elects, in its sole discretion, to do so, and such space leased to affiliates, subsidiaries or related entities, or vacant space, shall in no event be deemed to be "available for lease" hereunder.

26.3Procedures for Exercising ROFO. At such time as the ROFO Premises becomes available for lease to Tenant, Landlord shall, subject to the provisions of this Section 26, give a written offer (the "**Offer**") to Tenant of the terms under which Landlord is prepared to lease the ROFO Premises to Tenant, including the Base Rent (which shall be based upon Landlord's good faith judgment of the fair market rental value of the ROFO Premises in question), Tenant's improvement allowance, if any, term, renewal term and all other material business terms. Tenant may lease the ROFO Premises under such terms, by delivering written notice (the "**Acceptance**") to Landlord accepting such Offer within ten (10) days after Landlord gives such Offer to Tenant, time being of the essence.

26.4Conditions to ROFO. The ROFO is subject to the following conditions, and, without limiting the foregoing, Landlord shall have no obligation to give an Offer to Tenant with respect to the ROFO Premises, or any portion thereof, if any of the following conditions ("**ROFO Conditions**") are not satisfied:

(i) no Event of Default by Tenant exists at the time that Landlord would otherwise deliver the Offer; or

(ii) no portion of the Premises is sublet (other than to an Affiliated Entity or Successor) at the time Landlord would otherwise deliver the Offer; or

(iii)the Lease has not been assigned (other than to an Affiliated Entity or Successor) prior to the date Landlord would otherwise deliver the Offer; or

(iv)at least three (3) years remain in the Term; or

(v) Tenant has a market capitalization of at least Five Billion and 00/100 Dollars ($5,000,000,000.00) for four (4) consecutive fiscal quarters immediately preceding and as of the ROFO Conditions Dates, as evidenced by supporting documentation reasonably acceptable to Landlord.

26.5Termination of Right of First Offer. Tenant's right to lease the ROFO Premises pursuant to this Section 26 shall, upon the earlier to occur of: (i) Tenant's failure to give a timely Acceptance with respect to such ROFO Premises within the ten-(10)-day period provided in Section 26.4 above; or (ii) the date Landlord would have provided Tenant an Offer with respect to such ROFO Premises if Tenant had not failed to satisfy one or more of the ROFO Conditions set forth in this Section 26, terminate, and Tenant shall have no further right to lease such ROFO Premises. If Landlord gives Tenant an Offer to lease only a portion of the ROFO Premises, then Tenant's right to lease such portion of the ROFO Premises pursuant to this Section shall, upon the earlier to occur of: (x) Tenant's failure to give a timely Acceptance with respect to such portion of such ROFO Premises within the ten-(10)-day period provided in Section 26.4 above; or (y) the date Landlord would have provided Tenant an Offer with respect to such portion of the ROFO Premises if Tenant had not failed to satisfy one or more of the ROFO Conditions set forth in this Section 26, terminate, and Tenant shall have no further right to lease such portion of the ROFO Premises.

26.6Terms of Lease Applicable ROFO Premises. The terms applicable to Tenant's demise of the ROFO Premises, or any portion thereof, shall be upon the terms set forth in the applicable Offer, and otherwise upon the terms and conditions of the Lease, to the extent that the provisions of the Lease are not inconsistent with such Offer, and as follows:

(i) The term for the ROFO Premises shall, subject to clause (iii) below, commence upon the commencement date stated in the Offer.

(ii) Tenant shall pay Base Rent and Additional Rent for such ROFO Premises, or portion thereof, in accordance with the terms and conditions of the Offer.

(iii)Such ROFO Premises shall be accepted by Tenant in its condition (including improvements and personalty, if any) and as-built configuration existing on the earlier of the date Tenant takes possession of such ROFO Premises, of portion thereof, or as of the date the term for such ROFO Premises, or portion thereof, commences, and Landlord shall have no obligation to provide any Landlord contribution or free rent with respect to such ROFO Premises, or portion thereof, unless otherwise provided in such Offer.

26.7Offering Amendment. If Tenant exercises the ROFO with respect to the ROFO Premises Landlord shall prepare an amendment (the "**Offering Amendment**") adding such ROFO Premises, or portion thereof, to the Premises on the terms set forth in the Offer and reflecting the changes in the Base Rent, Rentable Square Footage of the ROFO Premises, Tenant's Share, and other mutually agreeable appropriate terms. A copy of the Offering Amendment shall be sent to Tenant within a reasonable time after Landlord's receipt of the Acceptance sent by Tenant to Landlord, and, if the terms and conditions of the Offering Amendment are reasonably acceptable to Tenant, then Tenant shall execute and return the Offering Amendment to Landlord within fifteen (15) days thereafter, but an otherwise valid exercise of the ROFO shall be fully effective whether or not the Offering Amendment is executed.

26.8Last Acceptance Date. If Tenant does not give Landlord a written Acceptance on or before the date ("**Last Acceptance Date**") which is ten (10) days after Landlord gives the Offer to Tenant, Landlord shall have the right to enter into a lease the subject ROFO Premises on any terms to any party

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF the parties hereto have executed this Lease as of the Execution Date.

LANDLORD:

HCP/KING 101 CPD LLC, a Delaware limited liability company

By: King/Mugar 101 CPD LLC,
a Delaware limited liability company, its Manager

By: King Martin LLC,
a Delaware limited liability company, its Manager

By: King Street Properties Investments LLC,
a Massachusetts limited liability company, its Manager

By: /s/ Stephen D. Lynch
Name: Stephen D. Lynch
Title: Manager

TENANT:

SERES THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Eric Shaff
Name: Eric Shaff
Title: President, Chief Executive Officer

Exhibit 10.26

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

CONFIDENTIAL

September 15, 2015

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "**Agreement**"), effective as of September 15, 2015 (the "**Effective Date**"), is made and entered into by and between Seres Therapeutics, Inc. (formerly Seres Health, Inc.), a corporation organized and existing under the laws of Delaware, having its principal place of business at 215 First Street, Cambridge MA 02142, USA ("**Seres**"); and GenIbet BioPharmaceuticals, SA, a corporation organized and existing under the laws of Portugal, having its principal place of business at Edifício da Unidade Piloto do IBET, Estação Agronómica Nacional, Avenida da República, 2780-157 Oeiras, Portugal ("**GenIbet**"). Seres and GenIbet may be referred to herein individually as a "**Party**" or collectively as the "**Parties**."

WHEREAS, Seres desires to have SER-109, SER-262, SER-287 and other products (each a "**Product**" and collectively, the "**Products**") manufactured by a third party for purposes of conducting clinical trials and commercial supply;

WHEREAS, GenIbet has expertise and cGMP-compliant facilities for the manufacture of products similar to the Products at its manufacturing facility located at Edifício da Unidade Piloto do IBET, Estação Agronómica Nacional, Avenida da República, 2780-157 Oeiras, Portugal (the "**Facility**");

WHEREAS, GenIbet desires to modify a manufacturing suite for the manufacture of the Products and to supply such Products to Seres, all in accordance with the terms and conditions of this Agreement.

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

Capitalized terms used but not defined in this Agreement shall have the meaning given in Exhibit 1.

2. AREAS

2.1 Dedicated Area in GenIbet's Facility.

2.1.1 GenIbet shall modify the dedicated bacterial suite (including fermentation, and purification rooms), the non-dedicated preparation room and access hallways as depicted on Exhibit 2 in the Facility for the performance of the activities relating to the Manufacture of the Products under this Agreement (the "**Seres Dedicated Area**"), and the raw materials and product storage areas depicted on Exhibit 2 in accordance with the construction plans and requirements attached hereto as Exhibit 2.

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2.1.2 GenIbet shall complete the construction, qualification and commissioning of the initial Seres Dedicated Area on or before [***] (the "**Deadline**"). The Deadline shall be equitably adjusted to reflect delays resulting solely from changes requested by Seres under Section 5 or otherwise by mutual agreement of the Parties.

2.1.3 GenIbet shall notify Seres upon completion of the Seres Dedicated Area that it is ready for acceptance. GenIbet shall provide Seres with all test results, evidence of conformance to applicable cGMP requirements, evidence of health, safety and environmental compliance as required under Section 9.7 hereof, and such other information reasonably requested by Seres for it to determine whether to accept or reject the Seres Dedicated Area.

2.1.4 Seres may only reject the Seres Dedicated Area if it does not fully comply with the agreed Project Plan and requirements of Exhibit 2. In this case, GenIbet shall correct the deficiencies so that the Seres Dedicated Area fully complies with the Project Plan and requirements of Exhibit 2 as promptly as possible and shall notify Seres that it is ready for acceptance. The date on which Seres accepts the Seres Dedicated Area is the "**Area Acceptance Date**". If the Area Acceptance Date is more than [***] after the Deadline, Seres may terminate this Agreement without liability or elect in its sole discretion to renegotiate the terms of this Agreement.

2.1.5 The use of the Seres Dedicated Area during the Term (as defined in Section 15.1) is solely for the purpose of Manufacturing the Products and for related activities benefitting Seres, and GenIbet shall not use the Seres Dedicated Area for any other purpose not approved in advance by Seres in writing. GenIbet agrees to make the Seres Dedicated Area available to Seres personnel and their designees as and when requested by Seres, provided that (i) the total number of people inside the units at the same time complies, at all times, with the provisions of cGMP; (ii) Seres personnel and their designees do not, at any time or in any way, compromise the Manufacturing process, and (iii) Seres personnel are trained in GenIbet SOPs required for their presence in the unit during Manufacturing.

2.2 Non-Dedicated Area in GenIbet's Facility

2.2.1 GenIbet will provide Seres with cGMP-compliant space that is sufficient for the Manufacture of Products in accordance with this Agreement, including (i) a preparation room; and (ii) storage spaces for Raw Materials, Consumables, process intermediates and Product (collectively, the "**Non-Dedicated Area**").

2.2.2 The storage spaces within the Non-Dedicated Area will have the appropriate environmental controls for temperature and humidity to meet the environmental storage requirements per the most relevant material specifications defined by the vendor or relevant pharmacopeia. These requirements shall be further specified in the appropriate documents and the Quality Agreements.

2.2.3 GenIbet's use of the Non-Dedicated Area for its other projects will not compromise: (i) Seres's Manufacturing schedule in the Seres Dedicated Area or the quality of the Raw Materials, Consumables, process intermediates and Product; or (ii) the cGMP compliance status of the Facility and activities related to the Manufacture of Product.

2.3 Seres Specialized Equipment.

2.3.1 Seres has or may provide the specialized equipment (non-permanent installation equipment) identified on Exhibit 2 for use by GenIbet in Manufacturing Product on behalf of Seres (the "**Specialized Equipment**"). GenIbet agrees not to use the Specialized Equipment in performing services for itself or for third parties.

2.3.2 GenIbet shall maintain the Specialized Equipment in accordance with the manufacturer's recommendations (other than as agreed with Seres) provided that the latest version of such recommendations is provided by Seres to GenIbet, as required to maintain the Specialized Equipment in accordance with this Agreement and the applicable Quality Agreement and otherwise in accordance with the maintenance plan set forth in the Product Manufacturing Plan.

2.4 Facility Closures. Within [***] after the Effective Date and on [***] thereafter, GenIbet shall propose to Seres a schedule showing all national and corporate holidays and Facility shutdowns for the next 12 months for Seres' review and approval. GenIbet shall not close the Facility on any day other than the dates identified in such schedule without Seres' prior approval.

3. DESCRIPTION OF WORK

3.1 Manufacture and Supply.

3.1.1 From and after the Area Acceptance Date, GenIbet shall Manufacture and supply to Seres the Products in accordance with a Master Batch Record. Notwithstanding the foregoing, before GenIbet commences Manufacture of a Product hereunder, the Parties shall agree in writing upon a Product Manufacturing Plan. Within [***] of the Effective Date, the Parties will agree a global Product Manufacturing Plan for SER-109, which will be incorporated into this Agreement as Exhibit 3.

3.1.2 The specifications for a Product set forth in the applicable Product Manufacturing Plan and/or Master Batch Record may be amended by Seres from time to time in accordance with Section 5.

3.2 Forecasts and Purchase Orders.

3.2.1 Within [***] after the Effective Date, Seres shall provide to GenIbet a non-binding [***] forecast of its estimated requests for each Product and update it within [***] after each calendar [***] (beginning on [***], so that GenIbet shall [***] rolling forecast as to the needs of Seres). Following receipt of each forecast, and without limiting its obligations to supply the Product in accordance with this Agreement, GenIbet shall promptly provide Seres [***] GenIbet's ability to provide the Product in accordance with such forecast.

3.2.2 Seres shall submit in writing or electronically purchase orders ("**Purchase Orders**") for the Product to GenIbet. If Seres submits a Purchase Order to GenIbet without providing at least the Minimum Lead Time, GenIbet will not be required to deliver the ordered Product by the requested delivery date, but will use Commercially Reasonable Efforts to deliver the Product in the Purchase Order on the requested date, but in any event shall deliver the Product within the applicable Minimum Lead Time. The "**Minimum Lead Time**" for SER-109 is [***], and for other Products shall be as set forth in the applicable Product Manufacturing Plan.

3.2.3 Unless GenIbet expressly notifies Seres otherwise, GenIbet shall be deemed to have accepted any and all such Purchase Orders from Seres; provided that Purchase Orders (other than the Last Time Buy under Section 15.7.5) that exceed the forecasts by more than [***]% in any calendar quarter for the purchase of the Product shall not bind GenIbet for the excess quantity until such Purchase Orders for such excess quantity are accepted by GenIbet. Each Purchase Order shall identify the Product being ordered, the quantity being ordered and the desired shipping date.

3.3 Staffing Plan.

3.3.1 Within [***] after the Effective Date, GenIbet shall prepare for Seres' review and approval a reasonable staffing plan. The staffing plan will include: at least [***], at least [***]. The [***] shall be agreed to by the Parties and stipulated in the applicable Purchase Order. Notwithstanding the foregoing, GenIbet shall employ a sufficient number of trained employees to ensure that GenIbet is able to meet its obligations under this Agreement, including Manufacture and delivery of Products in accordance with this Agreement (including delivery of the Products on or before the delivery date specified in the applicable Purchase Order).

3.3.2 GenIbet shall use Commercially Reasonable Efforts to guarantee that any absences due to illness and vacation of the trained personnel will not affect the compliance of its obligations, up to and including retaining appropriately experienced and trained staff for overtime work at its own expense.

3.3.3 The persons dedicated to Manufacture of Product may work on the manufacture of products for GenIbet or its other customers upon approval from Seres, which shall not be unreasonably withheld or delayed. Work for other customers shall not compromise cGMP compliance or delivery dates for the Products.

4. MATERIALS

4.1 Supply of Proprietary Materials. Except as otherwise set forth in the applicable Product Manufacturing Plan, Seres or its designees shall obtain and supply to GenIbet those certain proprietary Materials specified in the Product Manufacturing Plan and/or Master Batch Record as necessary to Manufacture the Product, within the deadlines foreseen in the Master Batch Record. Seres shall further provide to GenIbet such data and information as necessary to apprise GenIbet of the proper storage and safe handling requirements for the Materials delivered by Seres or its designees.

4.2 Non-Proprietary Materials. Seres or its designees shall instruct GenIbet regarding non-proprietary materials which will need to be obtained directly by GenIbet, including, but not limited to, type of materials, supplier/place of purchase and proper storage and safe handling requirements.

4.3 Inspection and Storage of Materials. GenIbet shall handle and store the Materials in accordance with this Agreement and the applicable Quality Agreement. GenIbet shall inspect and release test the Materials to ensure that they meet the Materials specifications set forth in the applicable Master Batch Record. GenIbet shall retain aliquots of each Material shipment per the Master Batch Record to enable regulatory compliance and investigations.

5. CHANGES TO PRODUCT AND/OR SERES DEDICATED AREA.

5.1 Each Party promptly shall notify the other Party of new regulatory requirements of which it becomes aware which may reasonably be expected to impact the requirements for the Manufacture of Product under this Agreement and which are required by an applicable Regulatory Authority or Applicable Law, and shall confer with each other with respect to the best means to comply with such requirements. GenIbet shall have no obligation to Manufacture Product in compliance with the requirements of a Regulatory Authority not explicitly specified in the Product Manufacturing Plan and/or Master Batch Record.

5.2 If changes to the Seres Dedicated Area, Product Manufacturing Plan, and/or Master Batch Record are required of the Parties as a result of requirements set forth by a Regulatory Authority, and such changes apply solely to the Seres Dedicated Area and Manufacture and supply of one or more Products, then Seres and GenIbet will review such requirements and agree in writing to changes to the Seres Dedicated Area, Product Manufacturing Plan, and Master Batch Record, and [***].

5.3 If changes resulting from the requirements of a Regulatory Authority apply generally to one or more Products as well as to other products produced by GenIbet for itself or for third parties, or to the Non-Dedicated Area, then Seres and GenIbet will review such requirements and agree in writing to changes to the Non-Dedicated Area, Product Manufacturing Plan, and Master Batch Record, and [***].

5.4 Subject to the foregoing, and notwithstanding anything to the contrary herein, GenIbet shall not make any changes to the Seres Dedicated Area, Non-Dedicated Area, Product Manufacturing Plan, and/or Master Batch Record that would reasonably be expected to have an impact on Seres or the Products [***].

6. MANUFACTURE

6.1 Testing Prior to Delivery. GenIbet shall conduct in-process testing of each Batch of Product according to the applicable Master Batch Record prior to delivery of such Batch by GenIbet to Seres or its designee. Unless exclusively due to any act or omission by Seres, if an in-process Batch of Product is not compliant with the Master Batch Record, GenIbet shall, [***], handle, store, transport, treat and dispose of such Product according to all applicable laws, directives, codes, rules, regulations, ordinances, orders, permits, licenses, consents and other authorizations (including but not limited to the environment and employee health and safety). Notwithstanding the foregoing, if reprocessing, rework or reproduction is allowed pursuant to Seres' regulatory submissions or approved by Seres, it shall be performed in accordance with the Quality Agreement and cGMP and, unless such reprocessing, rework, or reproduction results from Seres' acts or omissions, [***] in connection with such reprocessing, rework or reproduction.

6.2 Facility. GenIbet shall Manufacture each Product at the Facility, utilizing the Seres Dedicated and Non-Dedicated Areas. GenIbet shall maintain, [***], the Facility (including, without limitation, the Seres Dedicated Area) in a state of repair and operating efficiency consistent with the requirements of cGMP and other Applicable Law.

6.3 In the event any change in the Product Manufacturing Plan for a Product requested by Seres or mandated by Applicable Law or any increase in order volume requested by Seres results in any regulatory or other costs to GenIbet, or requires that GenIbet make any expenditures at the Facility or within the Seres Dedicated Area or Non-Dedicated Area, such costs and expenditures shall be [***].

6.4 Acceptance and Rejection

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6.4.1 GenIbet shall deliver to Seres, concurrently with the delivery of each Batch of Product, a Certificate of Compliance and such other documents and materials required to be delivered under the applicable Quality Agreement. Within [***] after delivery of any Batch of Product to Seres, Seres shall examine such Batch to determine whether the Product conforms to the Master Batch Record. No claims for non-compliance with the Master Batch Record or shortage in quantity of any individual shipment of any Product shall be valid unless made by written notice given within [***] from the date of delivery, except in the case of latent defects (defects not reasonably ascertainable upon a physical inspection of the Batch), in which case such claims shall be made in writing within [***]. Any such notice shall describe [***]. Failure to deliver a notice of non-conformance in the manner contemplated in this Section 6.4.1 shall constitute an acceptance of the applicable Batch by Seres.

6.4.2 If Seres notifies GenIbet under Section 6.4.1 that a shipment of Product has failed, in whole or in part, to meet the Master Batch Record, Seres will conduct [***]. If Seres determines that any part of the shipment fails to meet the Master Batch Record, Seres will provide [***] the results of Seres' testing; it being understood and agreed [***] proprietary.

6.4.3 If the affected Product fails to conform to the Master Batch Record, GenIbet shall make up any shortfall and/or replace any non-conforming Product or rework any rejected Product, if applicable, [***]; provided that GenIbet shall have no liability or obligation to Seres under this Section 6.4.3 if any such defect or non-conformance is not due to [***]. Upon GenIbet's instructions, Seres shall destroy or return, in either case at [***], any non-conforming Product; provided that if it is determined that any such defect or non-conformance is not due to [***].

6.5 Delivery. GenIbet shall deliver all Product FCA (Incoterms 2010) at the Facility. To the extent that Seres complies with the delivery dates regarding the supply to GenIbet of Materials and Specialized Equipment, GenIbet shall deliver to Seres the amount of Product specified in each Purchase Order no later than the dates specified therein. On or before the delivery date specified in the applicable Purchase Order, GenIbet shall, as directed by Seres, deliver the Product to a carrier designated by Seres or into storage at the Facility. All Purchase Orders shall be filled in compliance with the terms and conditions of this Agreement and the Master Batch Record, including any packaging, handling, storage and labeling requirements set forth on the Master Batch Record.

6.6 Storage. GenIbet will store Products [***] after GenIbet's release or the period required by applicable cGMPs, whichever is longer (the "**Storage Period**"). The Storage Period may be extended only if agreed to by the Parties in writing. After the Storage Period, if GenIbet agrees to store Product longer, then GenIbet may charge the storage fees as set forth in Exhibit 4. GenIbet shall store all Products in accordance with Applicable Law and Seres' reasonable instructions. Notwithstanding anything to the contrary in the foregoing, with respect to Product intended for commercial distribution, GenIbet shall maintain the amount of safety stock (the "**Safety Stock**") of each Batch of Product in quantities to be agreed upon by the Parties in good faith at least [***] prior to the first expected delivery date of Product for commercial distribution. Such Safety Stock shall be stored in accordance Seres' reasonable instructions and cGMPs, and shall be maintained for the period required by cGMPs, unless the Product Manufacturing Plan sets forth a longer period.

6.7 [***].

7. INTELLECTUAL PROPERTY

7.1 Existing Intellectual Property. Except as the Parties may otherwise expressly agree in writing, each Party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property, without conferring any interests therein on the other Party. Without limiting the generality of the preceding sentence, as between GenIbet and Seres, Seres shall own all right, title and interest arising under Applicable Law in and to all Products, Seres technology and labeling and trademarks associated therewith, including any improvements and modifications relating thereto, and any Inventions based on Seres' Confidential Information (collectively, **"Seres Intellectual Property"**). Neither GenIbet nor any third party shall acquire any right, title or interest in Seres' Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein. GenIbet hereby assigns (and will cause its personnel and any third parties involved in the performance of its obligations hereunder to assign) to Seres, without further compensation being due, any right, title and interest they may have in any Seres Intellectual Property. GenIbet agrees to take such steps and execute such documents as may be reasonably requested by Seres to perfect Seres' ownership of Seres' Intellectual Property.

7.2 License.

7.2.1 Subject to the terms of this Agreement, Seres will grant GenIbet on the Area Acceptance Date a non-exclusive, royalty-free, revocable license to (i) make the Products in the Seres Dedicated Area; and (ii) use the trademarks of Seres identified in the Product Manufacturing Plan solely in connection with its labeling of Products, in each case during the Term and solely at the Facility. Such licenses shall not be sublicensable, assignable or transferable in whole or in part. GenIbet's use of Seres' trademarks shall comply with Seres' usage guidelines. GenIbet hereby assigns to Seres all goodwill associated with the use of Seres' trademarks. In the event that GenIbet becomes aware of any possible or actual infringement by a third party of Seres' Intellectual Property, it shall provide immediate written notice to Seres.

7.2.2 GenIbet hereby grants (and shall cause any third party licensors of Licensed Know-How to grant) Seres a non-exclusive, transferable, royalty-free, irrevocable, perpetual, worldwide license to use and modify any GenIbet Intellectual Property, together with a right to sublicense the GenIbet Intellectual Property and Licensed Know-How to any third party manufacturer solely for purposes of manufacturing products for Seres and its Affiliates and business partners. "**GenIbet Intellectual Property**" means any processes or know-how owned by or licensed to GenIbet that GenIbet uses to Manufacture the Products for Seres under this Agreement.

7.3 Technology Transfer. Subject to the terms of this Agreement, Seres shall promptly provide GenIbet all the documentation, information, Specialized Equipment (including specifications therefor), and materials that are necessary for the Manufacture of the Products. All such documentation, information, Equipment and materials shall remain the sole and exclusive property of Seres.

7.4 Disclaimer. Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, or otherwise, as: (i) a grant, transfer or other conveyance by either Party to the other of any right, title, license or other interest of any kind in any of its Inventions or other intellectual property, (ii) creating an obligation on the part of either Party to make any such grant, transfer or other conveyance or (iii) requiring either Party to participate with the other Party in any cooperative development program or project of any kind or to continue with any such program or project.

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7.5 Confidentiality of Intellectual Property. Intellectual Property shall be deemed to be the Confidential Information of the Party owning such Intellectual Property. The protection of each Party's Confidential Information is described in Section 11.

8. SUBCONTRACTORS

GenIbet shall not subcontract its obligations under this Agreement (other than with respect to the construction of Seres Dedicated Area) without the prior written consent of Seres, which consent shall not be unreasonably withheld or delayed. [***]. GenIbet shall cause its subcontractors to execute agreements with provisions substantially similar to the provisions in Sections 7, 11, and 12.2. Seres may revoke its approval of a subcontractor if the subcontractor breaches Section 7, 11, and 12.2 in any material respect.

9. REGULATORY AND QUALITY MATTERS

9.1 Permits, Registrations and Licenses.

9.1.1 Seres will be responsible, [***], for obtaining, maintaining, updating and remaining in compliance with all permits, licenses and other authorizations during the Term of this Agreement, which are necessary or required under federal, state, and local laws, rules and regulations which are applicable to the use of Product Manufactured by GenIbet hereunder. GenIbet will be responsible for, [***], obtaining and maintaining all generally required permits, registrations and licenses applicable to the Facility and to the production of pharmaceutical and biological products generally to the extent required for GenIbet to carry out its regulatory and Manufacturing obligations hereunder.

9.1.2 Without limitation on the foregoing in Section 9.1.1, GenIbet will prepare and deliver to Seres a Site Master File (SMF) in accordance with the Quality Agreement. Seres may utilize the SMF only in connection with the preparation of regulatory filings related to the Products. Any other use of the SMF by Seres shall require the prior written approval of GenIbet.

9.2 Quality Agreement. Within [***] of the Effective Date, the Parties shall agree in writing to a revised Clinical Quality Agreement and within [***] of the Effective Date, the Parties shall agree in writing to a Commercial Quality Agreement. [***]. The Quality Agreements are intended to supplement this Agreement, and shall be incorporated in this Agreement in its entirety, except that in the event of a conflict between any term, condition or provision of this Agreement and any term, condition or provision of the Quality Agreements, the applicable term, condition or provision of the Quality Agreement shall control unless specifically set forth otherwise in this Agreement or otherwise agreed in writing by the Parties.

9.3 Facility Audits. Representatives (including internal and external auditors) of Seres and its Affiliates (a) shall upon [***] review GenIbet's quality control procedures; and (b) may, during normal business hours and [***], conduct a supplier audit of the Facility and Seres Dedicated Area. GenIbet shall make available the Facility, Seres Dedicated Area and its personnel to representatives (including internal and external auditors) of Seres and its Affiliates for purposes of verifying that the Products are being Manufactured and supplied in accordance with the applicable Specifications and Applicable Law and that GenIbet is in compliance with the terms of this Agreement. GenIbet shall promptly remedy or cause the remedy of any deficiencies that may be noted in any such audit.

9.4 Inspections by Regulatory Authorities. Seres shall give GenIbet advance notice, to the extent that advance notice is given to Seres, of any site visit to the Facility by any Government Authority, the

purpose of which is to inspect the Manufacture of any Product or the compliance status of the Facility under Applicable Law, in accordance with the terms and conditions of the Quality Agreements. In any event, GenIbet shall advise Seres of the occurrence of any such visit immediately upon such visit, and GenIbet shall furnish to Seres all material information supplied to, or supplied by, any Government Authority, including the Form 483 (and foreign equivalent) observations and responses, to the extent that such information relates to such Product or the ability of GenIbet to comply with the terms of this Agreement or Applicable Law. In addition, and without limitation on the foregoing, to the extent permitted by the applicable Government Authority, representatives of Seres shall be permitted to participate in any such site visit by a Government Authority, and GenIbet shall provide Seres with a reasonable opportunity to review and comment upon any response to the Government Authority to the extent the response relates to Product prior to delivery to the Government Authority.

9.5 Adverse Event Reporting. Seres shall be responsible for reporting adverse events and complaints with respect to any Product (including the Materials), and for responding to any such reports and complaints, in accordance with the terms and conditions of the applicable Quality Agreement. GenIbet shall promptly notify Seres of any information GenIbet receives related to an adverse event or complaint.

9.6 Recalls. In the event Seres is required to recall any Product, or elects to institute a voluntary recall, Seres will be responsible for coordinating such recall. Seres will promptly notify GenIbet of such recall and provide GenIbet with a copy of all documents relating to such recall. GenIbet will cooperate with Seres in connection with any recall, [***], unless the recall is determined to have been necessitated by [***] to perform the Manufacturing activities at issue in accordance with Applicable Law or this Agreement. [***] will be responsible for all of the costs and expenses of recalls (including but not limited to costs associated with receiving and administering the recalled Product and notification of the recall to those persons whom Seres deems appropriate)), except for recalls determined to have been necessitated by [***] to perform the Manufacturing activities at issue in accordance with Applicable Law or this Agreement, in which case [***] will be responsible for all of the costs and expenses of such recalls.

9.7 Health, Safety and Environmental Compliance. All Manufacturing operations are to be performed using appropriate safety measures and containment techniques as dictated by Applicable Law and industry standards. GenIbet shall be solely responsible for implementing and maintaining health and safety procedures for the Manufacture of Product and performance of services under this Agreement and for the handling of any materials or hazardous waste used in or generated by such activities. GenIbet, in consultation with Seres, shall develop safety and handling procedures for Materials and Product; provided, however, that Seres shall have no responsibility for GenIbet's health and safety program. The generation, collection, storage, handling, transportation, movement and release of hazardous materials and waste generated in connection with the Manufacture of Product and other services under this Agreement shall be the responsibility of GenIbet at GenIbet's cost and expense, unless otherwise agreed to in writing by the Parties for special situations or conditions. Without limiting other legally applicable requirements, GenIbet shall prepare, execute and maintain, as the generator of waste, all licenses, registrations, approvals, authorizations, notices, shipping documents and waste manifests required under Applicable Law.

9.8 Distribution within European Union. In the event that Seres seeks to distribute Product, including as an investigational medicinal product, within the European Union or any member states thereof, Seres will be responsible [***] for obtaining all permits, licenses and other authorizations required by Applicable Law.

10. CHARGES, INVOICING, PAYMENT AND TAXES

10.1 Charges.

10.1.1 The Charges under this Agreement are set forth in Exhibit 4.

10.1.2 The Charges under Section 1 of Exhibit 4 shall be adjusted [***] for fluctuations in the exchange rate between the United States Dollar and the Euro. The adjustment shall be as follows:

(Current Exchange Rate - Baseline Exchange Rate) / Baseline Exchange Rate, where

"Baseline Exchange Rate" means the Euro to Dollar exchange rate, as quoted in the Wall Street Journal published [***].

"Current Exchange Rate" means the Euro to Dollar exchange rate, as quoted in the Wall Street Journal published [***].

10.2 Invoicing.

10.2.1 GenIbet shall promptly invoice Seres for the fixed monthly charges under Section 1 of Exhibit 4 and the [***] under Section 2 of Exhibit 4 on a monthly basis in arrears. GenIbet shall send invoices to [***].

10.2.2 GenIbet shall invoice Seres for the per-Batch charges [***] for each Batch in accordance with Section 3 of Exhibit 4.

10.3 Payment Terms. Except as otherwise stated in Exhibit 4, Seres shall pay all undisputed amounts pursuant to this Agreement within [***] after receipt of an invoice therefor from GenIbet by direct wire transfer of United States Dollars in immediately available funds in the requisite amount to [***].

10.4 Disputed Amounts. In the event of any dispute on the amounts, [***].

10.5 Taxes

10.5.1 Retained Taxes. Each Party will be responsible for the payment of any taxes, levies and charges on its own personal and real property, business and franchise and privilege taxes on its business, and for taxes based on its net income or gross receipts ("**Income Taxes**"), in each case that are imposed by applicable Government Authorities (collectively, the "**Retained Taxes**"). If required by Applicable Law, Seres will be entitled to withhold an amount in respect of any Income Tax from any payment to GenIbet only to the extent GenIbet does not benefit of any exemption of withholding tax under applicable tax treaties or to the limit of any reduced withholding tax GenIbet may benefit under applicable tax treaties. Seres shall inform GenIbet in writing in advance of any such required tax withholding, as well as, of any reduced withholding tax or exemption of withholding tax GenIbet may benefit under applicable tax treaties and the respective formalities. If any amounts in respect of Income Taxes are withheld by Seres, Seres shall pay such amounts over to the applicable Governmental Authority and provide documentation to GenIbet evidencing such payment.

10.5.2Export/Import Taxes. [***] shall be responsible for the taxes, duties, tariffs, consular fees, levies, penalties, and other charges imposed by applicable Governmental Authorities on the import or export of the of Products ("**Export/Import Taxes**") to the extent such Party is responsible for such amounts in accordance with the Incoterms® 2010 delivery terms set forth in Section 6.5.

10.5.3Other Taxes. [***] shall be responsible for all goods, VAT, sales, use, consumption and other similar taxes, levies and charges (other than Retained Taxes and Export/Import Taxes) imposed by applicable Governmental Authorities in connection with the delivery of the Products to Seres or any invoice. [***].

1.1.1EU VAT Directive. Cross-Border sales of Products may fall within Article 44 of the EU VAT Directive or the relevant equivalent national provision, so that GenIbet is not required to charge VAT. In such case, with respect to each applicable jurisdiction, [***].

1.1.1Cooperation. Each Party shall cooperate, as reasonably requested by the other, to minimize the amount of all amounts payable to Government Authorities under this Section 10.5, including by claiming any available exemption or any available refund, credit or other recovery, and by executing and filing any invoices, forms or certificates reasonably required, in each case, to the extent that doing so would not adversely affect such Party.

10.6Audits. GenIbet shall maintain full and accurate financial records pertaining to amounts invoiced under this Agreement on a consistent basis and in accordance with GAAP for [***] after their creation or such longer period as may be required under Applicable Law. Such records shall include [***]. Upon Seres' request, GenIbet will provide Seres or its independent auditor with access to [***].

10.7Foreign Corrupt Practices Act. The Parties confirm that any compensation payable hereunder does not constitute remuneration or other means to attempt to corruptly influence a Government Official (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977 (the "**FCPA**")) to act in his official capacity to assist either Seres or GenIbet in obtaining or retaining business. In connection with each Party's obligations under this Agreement, and to the extent the FCPA applies to either Party's obligations under this Agreement, neither Seres nor GenIbet has made or offered, or hereafter will make or offer, directly or indirectly, any payment or inducement to a Government Official with the intent to corruptly influence a Government Official to act in his official capacity to assist either Seres or GenIbet in obtaining or retaining business. In connection with this Agreement, neither Party will give to or accept from any other person anything of value in order to obtain an improper business advantage. Any breach of the foregoing provision will be deemed a material breach of this Agreement that is not capable of relief and will entitle the nonbreaching Party to terminate this Agreement with immediate effect.

11. CONFIDENTIALITY

11.1Confidentiality Obligations. Each Party agrees that such Party will use reasonable efforts to keep confidential any Confidential Information of the other Party. The foregoing obligations will not apply to any information to the extent that:

11.1.1 Was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

11.1.2 Was generally available to the public or was otherwise part of the public domain at the time of its disclosure to the receiving Party;

11.1.3 Became generally available to the public or otherwise becomes part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

11.1.4 Was subsequently lawfully disclosed to the receiving Party by a third party other than in contravention of a confidentiality obligation of such third party to the disclosing Party.

Each Party may disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, advising investors and the investment community of the results of activities hereunder (subject to the prior written consent of the other Party, which consent will not be unreasonably withheld), complying with applicable governmental regulations, granting a permitted sublicense of its rights hereunder or otherwise in performing its obligations or exercising its rights hereunder. If a Party is required to make any such disclosure of the other Party's Confidential Information, it will give reasonable advance notice to that other Party of such disclosure requirement, will cooperate with the other Party in its efforts to secure confidential treatment of such Confidential Information prior to its disclosure, and, except to the extent inappropriate in the case of patent applications, will use all reasonable efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or confidentiality agreements or otherwise).

11.2Public Announcement; Agreement Terms. Except to the extent required by Applicable Law, neither Party shall make any public announcements concerning this Agreement or the terms hereof without the prior written consent of the other Party. The terms and conditions of this Agreement shall be Confidential Information of the Parties.

12. REPRESENTATIONS, WARRANTIES, UNDERTAKINGS, AND COVENANTS

12.1By Each Party. Each Party represents, warrants, undertakes and covenants to the other that: (i) it is duly organized and validly existing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement; (ii) it has all necessary power and authority to execute and deliver this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated hereby; (c) its execution and delivery of this Agreement have been duly and validly authorized by all necessary action, and no other proceedings on its part are necessary to authorize this Agreement or to consummate the transactions contemplated hereby; and (iii) this Agreement has been duly authorized and validly executed and delivered by it and constitutes a legal, valid and binding obligation on it, enforceable against it in accordance with the terms of this Agreement.

12.2By GenIbet. GenIbet represents, warrants, undertakes and covenants that: [***].

12.3Disclaimer of Warranties. EXCEPT AS SPECIFICALLY SET FORTH IN THIS SECTION 12, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT AND ANY OTHER STATUTORY WARRANTY.

13. INDEMNIFICATION

13.1 Indemnification by Seres. Seres shall indemnify, defend and hold GenIbet and its Affiliates, agents, employees, officers and directors (the "**GenIbet Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) arising out of third party claims or suits related to: (a) Seres' performance of, or failure to perform, its obligations under this Agreement; (b) breach by Seres of any of its representations, warranties, covenants and undertakings under this Agreement; and (c) GenIbet's use of the Seres Intellectual Property in the manner expressly permitted under this Agreement; provided, however, that Seres' obligations pursuant to this Section 13.1 will not apply to the extent such claims or suits result from the acts or omissions of any of the GenIbet Indemnitees or to the extent such claims or suits are the responsibility of GenIbet under Section 13.2.

13.2 Indemnification by GenIbet. GenIbet shall indemnify, defend and hold Seres and its Affiliates and business partners, and their respective agents, employees, officers and directors (the "**Seres Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) arising out of Third Party claims or suits related to: (a) GenIbet's performance of, or failure to perform, its obligations under this Agreement; (b) breach by GenIbet of any of its representations, warranties, covenants and undertakings under this Agreement; and (c) [***].

13.3 Notification of Claim . A Party seeking indemnification shall: (a) promptly notify ("**Claim Notice**") the indemnifying Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto (provided that the failure to give a Claim Notice promptly shall not prejudice the rights of an indemnified Party except to the extent that the failure to give such prompt notice materially adversely affects the ability of the indemnifying Party to defend the claim or suit); (b) cooperate with the indemnifying Party in the defense of such claim or suit, at the expense of the indemnifying Party; and (c) if the indemnifying Party confirms in writing to the indemnified Party its intention to defend such claim or suit within [***] after receipt of the Claim Notice, permit the indemnifying Party to control the defense of such claim or suit, including without limitation the right to select defense counsel; provided that if the indemnifying Party fails to (i) provide such confirmation in writing within the [***] period; or (ii) diligently and reasonably defend such suit or claim at any time, its right to defend the claim or suit shall terminate immediately upon [***] written notice to the indemnifying Party and the indemnified Party may assume the defense of such claim or suit [***]. In no event, however, may the indemnifying Party [***].

14. DISPUTE RESOLUTION

14.1 Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration under the [***], which Rules are deemed to be incorporated by reference into this clause.

14.2 The number of arbitrators shall be [***]. The seat, or legal place, of arbitration shall be [***]. The language to be used in the arbitral proceedings shall be English.

14.3 The Parties further consent to the jurisdiction of any state court located within a district that encompasses assets of a Party against which a judgment has been rendered for the enforcement of such judgment or award against the assets of such Party.

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15. TERM AND TERMINATION

15.1Term. This Agreement will commence upon the Effective Date and shall continue in full force and effect for the period of [***] after the Effective Date, unless terminated earlier in accordance with this Agreement or extended in accordance with this Section 15.1 (the "**Term**"). Seres may extend the Term [***] on the then-current terms and conditions.

15.2Termination for Convenience. Subject to the early termination fees in Section 15.3 of this Agreement, Seres may terminate this Agreement [***].

15.3Early Termination Fees. In the event that Seres terminates the Agreement under Section 15.2 prior to the third anniversary of the Effective Date has expired, the following early termination fees will apply:

15.3.1[***];

15.3.2[***];

15.3.3[***].

15.4Termination for Cause.

15.4.1 Seres may terminate this Agreement upon a date set forth in a notice of termination if GenIbet breaches a material obligation under this Agreement and fails to cure it within [***] after notice of termination by Seres. Any such notice shall describe, in detail, the breach of the material obligation.

15.4.2 GenIbet may terminate this Agreement upon a date set forth in a notice of termination if Seres fails to make any payment in accordance with Section 10.3 and Exhibit 4 and fails to cure such failure within [***] after notice of termination.

15.5Termination for Insolvency. To the extent permitted under Applicable Law, within [***] after receiving notice of any of the following events, GenIbet with respect to Seres, and Seres with respect to GenIbet, shall have the right to terminate this Agreement forthwith on written notice: (a) dissolving or ceasing to do business; (b) making an assignment for the benefit of creditors; (c) being subject to the institution of insolvency, receivership, bankruptcy or other proceedings for settlement of debts, provided such proceedings have not been vacated within [***] and are being actively contested by such other Party; or (d) effecting a reorganization of its business or affairs using any creditor protection legislation.

15.6Termination for Change of Control. Seres may [***] if there is a Change of Control of GenIbet.

15.7Effect of Expiration or Termination.

1.1.1 In the event of termination or expiration of this Agreement, the Parties will endeavor to transition the Manufacturing services and technology transfer in such a manner as to not cause unreasonable inconvenience to either Party. The Parties will reasonably cooperate during such period to continue any such ongoing services and GenIbet shall perform such

functions reasonably necessary or required in connection with the orderly wind-down of any active project as required by the terms of this Agreement and Applicable Law.

1.1.1 Promptly upon a termination of this Agreement or at the request of the disclosing Party, the receiving Party shall return to the disclosing Party all Confidential Information of the disclosing Party in its possession, except for one copy that may be retained solely for archive purposes in a confidential legal file. Furthermore, GenIbet shall promptly return all Seres-supplied Materials, Seres-supplied or paid-for equipment (including the Specialized Equipment), records, Product, retained samples, reference standards, data, reports and other property, information and/or know-how in recorded form that was provided by Seres, or generated in the performance of the services under this Agreement, that are owned by or licensed to Seres, excepting that required to be retained by Applicable Law, litigation holds or for regulatory compliance.

1.1.2 In the event of termination by GenIbet pursuant to Section 15.4 (Termination for Cause), Seres shall pay GenIbet for Manufacturing and other services completed up to the effective date of such termination within [***] of Seres' receipt of all results, reports, data, samples, and other deliverables to be provided pursuant to this Agreement. In the event the funds received by GenIbet prior to such termination exceed costs incurred to the date of termination, GenIbet shall refund the difference to Seres within [***] after the effective date of termination.

1.1.3 Upon any termination of this Agreement other than for GenIbet's material breach, Seres: (i) shall purchase from GenIbet any existing inventories of Product conforming to the Master Batch Record and Manufactured in accordance with cGMP and the Master Batch Record, at the then-current per-Batch charge for the Manufacture of such Product under Section 3 of Exhibit 4; and (ii) may either: (a) purchase any Product in process held by GenIbet as of the date of the termination, at a price to be mutually agreed (it being understood that such price shall reflect, on a *pro rata* basis, work performed and non-cancelable, out-of-pocket expenses actually incurred by GenIbet with respect to the Manufacture of such in-process Product); or (b) reimburse GenIbet for all work performed and non-cancelable costs, and out-of-pocket expenses incurred by GenIbet and direct GenIbet to dispose of such material at [***] cost.

1.1.4 Upon a termination of this Agreement under Section 15.6, GenIbet (or its successor) shall: (i) continue to fill orders for Products submitted during the Run-Down Period; and (ii) fill a final order (the "**Last Time Buy**") for Products notwithstanding the then-current forecast. GenIbet or its successor will maintain the ability to produce up to 24 Drug Substance and 24 Drug Product lots for a Last Time Buy during the Run-Down Period. The "**Run-Down Period**" means the 12 month period commencing on the effective date of termination.

1.2 Survival. The following Sections of this Agreement shall survive its termination for any reason: 2.1.4, 2.3, 6.6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17.3, 17.5, 17.6, 17.7, 17.8, 17.9, 17.10, 17.11, and 17.12.

2. INSURANCE

15.8 GenIbet shall provide the following insurance coverage in the amounts specified:

2.1.1[***].

2.1.2[***].

2.1.3[***].

15.9 The foregoing insurance covers shall be primary and non-contributing with respect to any other insurance or self-insurance that may be maintained by Seres and its Affiliates. [***]. GenIbet shall cause its insurers to issue a letter from the applicable insurer that evidences that the covers and policy endorsements required under this Agreement are maintained in force. The insurers selected by GenIbet shall have an [***] rating of [***] or better.

15.10 In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than [***] following the termination or expiration of the Term. During the Term and such [***] period, GenIbet shall use Commercially Reasonable Efforts not to permit any insurance set forth in Section 16.1 to be reduced, expired or canceled without the prior written consent of Seres**.**.

3. MISCELLANEOUS

3.1 Independent Contractors. This Agreement does not create a joint venture, partnership, employment relationship or other agency relationship between the Parties or their Affiliates. Neither Party shall be obligated with respect to any transaction and no obligation or rights or liabilities of any kind whatsoever are created (or shall be deemed to be created) as a result of this Agreement, or any other written or oral statement or any further actions by the Parties, except in the case of this Agreement for the provisions expressly contained herein.

3.2 Assignment. Except to the extent and in the manner provided in this Section 17.2, the Parties agree that their rights and obligations under this Agreement may not be transferred or assigned to a third party without the prior written consent of the other Parties, which consent may be withheld in each such other Party's sole discretion. Any assignment not in conformance with this Section 17.2 shall be null, void and of no legal effect. Notwithstanding the foregoing:

3.2.1a Party may transfer or assign its rights and obligations under this Agreement, without consent, to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise;

3.2.2 Seres may transfer or assign its rights and obligations under this Agreement without consent to an Affiliate; and

3.2.3 GenIbet may transfer or assign its rights and obligations under this Agreement without consent to an Affiliate that is at least as creditworthy as GenIbet.

3.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the express provisions of this Agreement.

3.4 Force Majeure. Neither Party shall be liable to the other Party for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, war, terrorist acts, flood, the other Party's non-performance, or other event that is both beyond the reasonable control of the respective Party and could not be avoided through

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reasonable precautions. The Party affected by such force majeure event will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If there is a force majeure event, the Party affected by the force majeure event is excused from any default or delay for as long as and to the extent that: (i) such circumstances prevail; (ii) the affected Party is not at fault in causing the force majeure event and could not have avoided the default or delay through the use of reasonable precautions; (iii) the affected Party continues to use its Commercially Reasonable Efforts to recommence performance. If the performance by GenIbet of any obligation under this Agreement is delayed owing to a force majeure for any continuous period of more than [***], Seres shall have the right to either (i) [***]; or (ii) [***].

3.5 Entire Agreement of the Parties; Amendments; Waiver. This Agreement constitutes and contains the entire understanding and agreement of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior and contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of this Agreement will be valid or effective unless made in writing and signed by each of the Parties. No waiver, modification or amendment of any other provision of this Agreement will be valid or effective unless made in writing and signed by both Parties. A waiver by either Party of any of the terms and conditions of this Agreement in any instance will not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof.

3.6 Captions. The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.

3.7 Governing Law. This Agreement shall be governed by, and construed and interpreted, in accordance with the internal laws of the [***] without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction. It is hereby agreed that the United Nations' Convention on Contracts for the International Sale of goods shall have no application to this Agreement and it is hereby specifically excluded.

3.8 Notices and Deliveries. Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) or [***] after it was sent by registered letter, return receipt requested (or its equivalent), provided that no postal strike or other disruption is then in effect or comes into effect within [***] after such mailing, to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party will have last given by notice to the other Parties.

If to Seres, addressed to:

Seres Therapeutics, Inc.
215 First St., Suite 100
Cambridge, MA 02142, USA
Attention: [***]
Fax:+16179450268

If to GenIbet, addressed to:

GenIbet Biopharmaceuticals
Estação Agronómica Nacional
Avenida da Rebública, 2780-157 Oeiras,Portugal
Attention: [***]
Fax:+351214469480

3.9 No Consequential Damages.

3.9.1 SUBJECT TO SECTION 17.9.2, IN NO EVENT WILL ANY PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE TO THE ANY OTHER PARTY OR ANY OF ITS AFFILIATES FOR: (I) SPECIAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, LOSS OF PROFITS OR REVENUE; OR (II) DIRECT DAMAGES IN EXCESS OF THE AMOUNTS PAID OR PAYABLE UNDER THIS AGREEMENT.

15.10.1 Section 17.9.1 shall not apply to a Party's obligations under [***].

3.10 Cumulative Remedies. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

3.11 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties will make a good faith effort to replace the invalid or unenforceable provision with a valid one so long as the essential benefits of this Agreement remain enforceable and obtainable.

3.12 Counterparts. This Agreement 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]

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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.

Seres Therapeutics, Inc.

By: /s/ Roger Pomerantz

Name: Roger Pomerantz, M.D.

Title: President and Chief Executive Officer

GenIbet BioPharmaceuticals

By: /s/ [***]

Name: [***]

Title: [***]

By: /s/ [***]

Name: [***]

Title: [***]

Exhibit 1

Definitions

As used in the Agreement, the following terms are defined as indicated:

"Active Pharmaceutical Ingredient" or **"API"** means the active pharmaceutical or biological ingredient as further set forth in the applicable Product Manufacturing Plan.

"Affiliate" means with respect to either Party, any business entity controlling, controlled by, or under common control with such Party. For the purpose of this definition only, "control" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a business entity; provided that, if local law requires a minimum percentage of local ownership, control will be established by direct or indirect beneficial ownership of one hundred per cent (100%) of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

"**Applicable Law**" shall mean all international, national, federal, state, provincial and local laws, statutes, codes, guidelines, rules, regulations, ordinances, orders, decrees or other pronouncements of any governmental, administrative or judicial authority that apply to either of the Parties' respective obligations hereunder, including cGMP.

"Batch" shall mean a specific quantity of product that (a) is intended to have uniform character and quality within specified limits, and (b) is Manufactured according to a single manufacturing order during the same cycle of manufacture as further specified in the applicable Product Manufacturing Plan.

"Certificate of Compliance" means a document signed by the designated quality manager of GenIbet in connection with the Manufacture of a Batch of Product that evidences such Batch's compliance with cGMPs and Master Batch Record.

"Change of Control" means the occurrence of any one of the following: (a) any person (as the term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) is or becomes the beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of voting securities of GenIbet representing more than 50% of GenIbet's outstanding voting securities or rights to acquire such securities; (b) any sale, lease, exchange or other transfer (in one transaction or a series of transactions) of the Facility or all or substantially all of the assets of GenIbet; or (c) a plan of liquidation of the Company or an agreement for the sale or liquidation of the Company is approved and completed.

"Commercially Reasonable Efforts" mean taking such steps and performing in such a manner as a well-managed company would undertake where such company was acting in a determined, prudent, and reasonable manner to achieve the particular result provided always that such steps are within the reasonable control of the Party required to exert such efforts.

"Confidential Information" means any and all non-public and proprietary information that is specifically designated as such and that is disclosed by any Party to any other Party in written or other

similar form in connection with this Agreement; provided, however, that in the case of such information that is disclosed orally, the disclosing party shall deliver the required designation in writing to the receiving Party within 30 days after such disclosure.

"Consumables" shall mean the consumable products and packaging supplies and components, including, without limitation, all of the raw materials and packaging supplied required by GenIbet to Manufacture a Product as set forth in the applicable Product Manufacturing Plan.

"Control" means, with respect to an item or an intellectual property right, possession of the ability, whether arising by ownership or license, to grant a license or sublicense as provided for in this Agreement under such item or right without violating the terms of any written agreement with any Third Party.

"Current Good Manufacturing Practices" or **"cGMP"** shall mean the following to the extent having jurisdiction over the Manufacture of a Product and/or the Facility and Seres Dedicated Area: (a) the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA regulations (including without limitation 21 CFR 210 and 211); (b) the Commission Directive 2003/94/EC, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, and any amendment thereto; (c) the Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products, and any amendment thereto; (d) the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community code relating to medicinal products for human use, and any amendment thereto; (e) the Guidelines on Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, approved by the European Commission and currently provided for at Eudralex - Volume 4 and any amendment thereto; (f) any local laws, statutes, codes, guidelines, rules, regulations, ordinances, orders, decrees or other pronouncements of any governmental, administrative authority enacting and/or implementing and/or regulating the provisions of (b) to (e), and (f) the PICS guidelines to good manufacturing practices in effect at any time during the Term of this Agreement. For the avoidance of doubt, when reference is made herein to "any amendment thereto" it shall include acts which supersede and replace the ones expressly provided for.

"Drug Product" shall mean the Drug Substance in its finished dosage form that is produced in accordance with the Master Batch Record.

"Drug Substance" shall mean the substance that is produced in accordance with the Master Batch Record and intended to be used in the manufacture of a drug product.

"FDA" shall mean the United States Food and Drug Administration or any successor entity thereto.

"FD&C Act" shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

"Government Authority TC "Government Authority" \f C \l "5" " means any supranational, national, regional, state or local government, court, governmental agency, authority, board, bureau, instrumentality, or regulatory body.

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“Intellectual Property” shall mean ideas, concepts, discoveries, inventions, developments, know-how, trade secrets, techniques, methodologies, modifications, innovations, improvements, writings, documentation, data and rights (whether or not protectable under state, federal or foreign patent, trademark, copyright or similar laws) or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.

“Inventions” shall mean any inventions, discoveries, innovations, methods, improvements, processes, techniques or other valuable developments, whether patentable or copyrightable or not, relating to Product, the API or their manufacture, arising out of the performance of services under this Agreement by GenIbet and/or any use of either Seres Intellectual Property and/or the API. For the avoidance of doubt, Inventions include Process Inventions, as defined below.

“Licensed Know-How TC "Government Authority" \f C \l “5” ” shall mean any and all technology, information, expertise, know-how, and/or trade secrets Controlled by GenIbet that is necessary or useful for the manufacture of the Product and/or the manufacture, use, sale, offer for sale, and importation of the Products.

“Manufacture,” “Manufacturing,” and **“Manufactured**” shall mean all operations of GenIbet in the scheduling, production, manufacturing, processing, packaging, labeling, testing, storage, quality control testing (including in-process, release, and stability testing when applicable) and release of Product.

“Master Batch Record” or **“MBR”** shall mean, with respect to each Product to be Manufactured hereunder, a formal set of instructions given by Seres for the Manufacture of each such Product. The MBR shall be developed and maintained in GenIbet’s standard format by GenIbet, as per Seres’ instructions and using master formulation and technical support.

“Materials” as used in this Agreement shall collectively mean all materials required for Manufacture of Product, including the API, Consumables, and Raw Materials.

“Process Inventions” shall mean any Inventions that are new manufacturing technologies, methods, processes or techniques, or are improvements to existing manufacturing technologies, methods, processes or techniques, and that are generally applicable to pharmaceutical products. For purposes of clarity, Process Inventions shall not include such Inventions that (i) are only applicable to Product, Seres Technology, the intellectual property of a collaborator and/or the API and/or (ii) require the use of Product, Seres Technology, the intellectual property of a collaborator and/or the API.

“Product Manufacturing Plan” shall mean an addendum to this Agreement for each Product Manufactured hereunder, which may include, without limitation, the Product, Product Specifications, Materials, Materials Specifications, Regulatory Authorities, the countries where such Product will be used in clinical trials, and pricing for such Product Manufactured under this Agreement.

“Purchase Order” shall mean written orders from Seres to GenIbet which shall specify (a) the quantity of Product ordered, (b) the minimum number of employees and their status (e.g., full-time dedicated or part-time dedicated) to be engaged, (c) shipping instructions (e.g. choice of container, temperature requirements), (d) requested delivery dates, and (e) delivery destinations.

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“Quality Agreement” shall mean individually, either the Clinical Quality Agreement or Commercial Quality Agreement and “**Quality Agreements**” shall mean the Clinical Quality Agreement and Commercial Quality Agreement collectively, both of which are addenda to this Agreement under which the Parties allocate the pharmaceutical responsibilities, as further set forth in Section 8.2.

“Raw Materials” shall mean all excipients, inactive ingredients and other substances used by GenIbet in the Manufacture of a Product, with the exception of API and Consumables, as specified in the applicable Product Manufacturing Plan.

“Regulatory Authority” shall mean those agencies or authorities responsible for regulation of the Product in the country where the Product is Manufactured and/or used in clinical trials.

“Site Master File” shall mean a document prepared by GenIbet containing specific and factual GMP information about the production and/or control of pharmaceutical manufacturing operations carried out at the Facility and any closely integrated operations at adjacent and nearby buildings.

“SOP” means GenIbet’s standard operating procedures applicable to the Manufacture of the Product.

Exhibit 2

Seres Dedicated Area Project Plan

[***]

Attachment 2-1

Dedicated Area

[***]

Attachment 3

Product Manufacturing Plan for SER-109

[***]

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Exhibit 4

Charges

[***]

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200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

September 14, 2020

GenIbet Biopharmaceuticals SA Via Email: [***]
Estação Acronómica Nacional
Avenida da República ACKNOWLEDGEMENT REQUESTED
2780-157 Oeiras, PORTUGAL

Attention: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement for an additional [***] on the now-current terms and conditions.

Please confirm receipt of this letter via email to [***]

Regards,

/s/John G. Aunins
John Auniņš, Ph.D.
Chief Technical Officer and Executive Vice President, CMC

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200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

September 07, 2021

GenIbet Biopharmaceuticals SA
Estação Acronómica Nacional
Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: [***]

Via Email: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through [***], on the now-current terms and conditions.

Please confirm receipt of this letter by providing your e-signature below.

Best Regards,

/s/ David S. Ege
David S. Ege
EVP & Chief Technical Officer

Accepted and Agreed:

/s/[***]
[***]

|||

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

December 6, 2021

GenIbet Biopharmaceuticals SA
Estação Acronómica Nacional
Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: [***]

Via Email: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through [***], on the now-current terms and conditions.

Please confirm receipt of this letter by providing your e-signature below.

Best Regards,

/s/David S. Ege
David S. Ege
EVP & Chief Technical Officer

Accepted and Agreed:

/s/[***]
[***]
12/9/2021

|||

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

March 22, 2022

Sent via email: [***]

GenIbet Biopharmaceuticals SA
Estação Acronómica Nacional
Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: [***]

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through June 30, 2023, on the now-current terms and conditions.

Best Regards,

/s/David S. Ege
David S. Ege
EVP & Chief Technical Officer

|||

200 Sidney Street
Cambridge, MA 02139
Tel: 617-945-9626
www.serestherapeutics.com

March 6, 2023

GenIbet Biopharmaceuticals SA **Via Email: raquel.fortunato@genibet.eu and Federal Express**
Estação Acronómica Nacional Avenida da República
2780-157 Oeiras, PORTUGAL
Attention: Raquel Fortunato

Re: Supply Agreement effective September 15, 2015, as subsequently amended and extended (the "Agreement") by and between Seres Therapeutics, Inc. ("Seres") and GenIbet BioPharmaceuticals SA ("GenIbet").

Dear [***]:

Pursuant to Section 15.1 of the Agreement, this letter serves as notice that Seres will extend the Term of the Agreement through June 30, 2024, on the now-current terms and conditions.

Best Regards,

/s/David S. Ege
David S. Ege
EVP & Chief Technical Officer

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-273794) and S-8 (No. 333-205253, 333-210171, 333-223514, 333-230092, 333-236824, 333-253776, 333-263134, and 333-270319) of Seres Therapeutics, Inc. of our report dated March 5, 2024 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 5, 2024

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 5, 2024

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 5, 2024

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, 2023 (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 5, 2024

/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, 2023 (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 5, 2024

/s/ David Arkowitz

David Arkowitz

Executive Vice President, Chief Financial Officer and Head of Business Development
(*Principal Financial and Accounting Officer*)

Exhibit 97.1

SERES THERAPEUTICS, INC.

POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

Seres Therapeutics, Inc. (the "***Company***") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of October 2, 2023 (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to current and former Officers of the Company. Each Officer shall be required to sign an acknowledgment pursuant to which such Officer will agree to be bound by the terms of, and comply with, this Policy; however, any Officer's failure to sign any such acknowledgment shall not negate the application of this Policy to the Officer.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company

or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board of Directors of the Company (the "***Board***") may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7. No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8. Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "***Other Recovery Arrangements***"). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other

right or remedy at law or in equity that may be available to the Company or an affiliate of the Company.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

"***Committee***" means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Financial Reporting Measure***" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non-GAAP/IFRS financial measures, as well as stock or share price and total equityholder return.

"***GAAP***" means United States generally accepted accounting principles.

"***IFRS***" means international financial reporting standards as adopted by the International Accounting Standards Board.

"***Impracticable***" means (a) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company has (i) made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the Company has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Officer***" means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Three-Year Period***" means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.