

**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, 2020

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
(State or Other Jurisdiction of
Incorporation or Organization)
200 Sidney Street – 4th Floor
Cambridge, Massachusetts
(Address of Principal Executive Offices)

27-4326290
(IRS Employer
Identification No.)

02139
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 the attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant based on the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on June 30, 2020, was \$219,853,799. 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 February 24, 2021, there were 91,549,412 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 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020 are incorporated herein by reference in Part III.

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I.</u>	
Item 1. <u>Business</u>	5
Item 1A. <u>Risk Factors</u>	35
Item 1B. <u>Unresolved Staff Comments</u>	69
Item 2. <u>Properties</u>	69
Item 3. <u>Legal Proceedings</u>	69
Item 4. <u>Mine Safety Disclosures</u>	69
<u>PART II.</u>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	70
Item 6. <u>Selected Financial Data</u>	71
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	72
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	90
Item 8. <u>Financial Statements and Supplementary Data</u>	90
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	90
Item 9A. <u>Controls and Procedures</u>	90
Item 9B. <u>Other Information</u>	91
<u>PART III.</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	92
Item 11. <u>Executive Compensation</u>	96
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	96
Item 13. <u>Certain Relationships and Related Transactions and Director Independence</u>	96
Item 14. <u>Principal Accountant Fees and Services</u>	96
<u>PART IV.</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	97
Item 16. <u>Form 10-K Summary</u>	99
<u>SIGNATURES</u>	100

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

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties and assumptions described under the sections in this report titled “Summary Risk Factors,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K.

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

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

TRADEMARKS, SERVICE MARKS AND TRADENAMES

We have proprietary rights to trademarks used in this Annual Report on Form 10-K, which are important to our business and many of which are registered under applicable intellectual property laws. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this Annual Report on Form 10-K are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks, service marks and trade names. This Annual Report on Form 10-K contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this Annual Report on Form 10-K are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies’ trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

SUMMARY RISK FACTORS

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

- We are a development-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

- Other than SER-109 and SER-287, we are early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.
- Our product candidates are based on microbiome therapeutics, which is an unproven approach to therapeutic intervention.
- Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Delays or difficulties in the enrollment of patients in clinical trials, could result in our receipt of necessary regulatory approvals being delayed or prevented.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we 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 Agreement, or the License Agreement, with Société des Produits Nestlé S.A., or Nestlé, the successor in interest to Nestec Ltd., is important to our business. If we or Nestlé fail to adequately perform under the License Agreement, or if we or Nestlé terminate the License Agreement, the development and commercialization of our CDI and IBD product candidates, including SER-109, SER-287, and SER-301, would be delayed or terminated and our business would be adversely affected.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- We rely on third parties for certain aspects of the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We may expand our operational capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We will continue to incur costs as a result of being a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.

Item 1. Business

Overview

We are a microbiome therapeutics company developing a novel class of live biotherapeutic drugs, which are consortia of microbes designed to treat disease by modulating the microbiome to treat or prevent disease by repairing the function of a disease susceptible microbiome to a non-disease state. We have an advanced drug pipeline with late-stage clinical assets and a differentiated microbiome therapeutics drug discovery and development platform including good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality.

Our highest priority is preparing the SER-109 biologics license application, or BLA, for submission to the Food and Drug Administration, or FDA; we are focused on completing acquisition of the required safety database necessary for approval to treat *Clostridioides difficile* infection or CDI, with SER-109. Additionally, using our microbiome therapeutics platform, we are focusing our resources on obtaining clinical results from our clinical programs in ulcerative colitis, or UC, a form of inflammatory bowel disease, or IBD, with SER-287 and SER-301, with SER-401 in patients with metastatic melanoma, and with SER-155 to prevent mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation, or allo-HSCT, or solid organ transplants.

SER-109, our lead clinical candidate, which has successfully completed a Phase 3 clinical study, is designed to rapidly modulate the gastrointestinal microbiome in patients with recurrent CDI. CDI is most often caused by the use of broad-spectrum antibiotics, which disrupt the gastrointestinal microbiome by decreasing microbial diversity, thus increasing susceptibility to infection by *Clostridioides difficile*, or *C. difficile*, a spore forming bacterium. *C. difficile* expresses toxins leading to debilitating diarrhea in infected patients, and can also cause more severe outcomes, such as inflammation of the colon (colitis), toxic megacolon and death. The U.S. Centers for Disease Control, or CDC, has identified CDI as one of the top three most urgent bacterial threats in the United States. It is the most common cause of hospital acquired infection in the United States and has overtaken methicillin-resistant *Staphylococcus aureus*, or MRSA, in incidence of disease. CDI is responsible for the deaths of over 20,000 Americans each year. There are approximately 453,000 cases of primary CDI within the United States each year and approximately 170,000 incidences of recurrent CDI. The standard of care for CDI is to treat with antibiotics. In many cases, antibiotic treatments may kill vegetative toxin-producing *C. difficile* bacteria thus resolving symptoms of *C. difficile*. However, these antibiotic treatments also kill beneficial bacteria indiscriminately, thus maintaining or exacerbating the disrupted microbiome, potentially making patients more susceptible to a recurrence of CDI. Furthermore, antibiotics do not eliminate *C. difficile* spores, allowing the spores to rapidly germinate in a disrupted microbiome and cause a recurrence of the infection. Published data suggests that the risk of recurrence is approximately 25% after the primary CDI and increases to greater than or equal to 40% after a first recurrence. SER-109, if approved, is intended to treat individuals with recurrent CDI, a patient population which includes approximately 170,000 individuals per year in the United States.

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores, which normally live in the healthy microbiome. SER-109 is designed to prevent further recurrences of CDI in patients with a history of multiple infections by modulating the disrupted microbiome to a state that resists *C. difficile* colonization and growth. We completed enrollment with 182 patients with multiply recurrent CDI in ECOSPOR III. The study was designed to evaluate patients for 24 weeks with the primary endpoint of comparing the *C. difficile* recurrence rate in subjects who receive SER-109 versus placebo at up to eight weeks after dosing. The SER-109 manufacturing purification process is designed to remove unwanted microbes thereby reducing the risk of pathogen transmission beyond donor screening alone.

In August 2020, we reported positive topline results from the interim analysis of the pivotal Phase 3 ECOSPOR III study evaluating SER-109 for multiply recurrent CDI. Those results showed that SER-109 administration resulted in a highly statistically significant absolute decrease of 30.2% in the proportion of patients who experienced a recurrence in CDI within eight weeks of administration versus placebo, the study's primary endpoint, and which remained consistent at 12-weeks end point with a 31.1% absolute decrease. At eight weeks of treatment, 11.1% of patients administered SER-109 experienced a CDI recurrence, versus 41.3% of placebo patients. The study results were equally compelling when characterized by the alternative metric of sustained clinical response, where 88.9% of patients in the SER-109 arm achieved this objective at eight weeks. Subsequent analyses from the completed Phase 3 study using the final statistically defined Intent-to-Treat population show that 12.4% of subjects experienced a recurrence, versus 39.8% on placebo, which represents a relative risk of 0.32 (95% CI 0.18-0.58; $p < .001$), with an absolute risk reduction of 27% and a relative risk reduction of 69%. The percent on SER-109 with a sustained clinical response was approximately 88%. The number-needed-to treat was 3.7. In the same updated analysis, the 12 week rate of recurrence in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65; p -value = 0.002), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study's efficacy results related to the primary endpoint from all analyses exceeded the statistical

threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a BLA. The efficacy remained durable through twenty-four weeks of follow-up.

The SER-109 safety results observed to-date were favorable, with an adverse event profile comparable to placebo. We are actively enrolling patients in our SER-109 open-label study, which also allows enrollment of patients with single or multiple recurrences of CDI, to expand the safety database to meet the FDA threshold of at least 300 patients.

SER-287, an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores, is designed to normalize the gastrointestinal microbiome of individuals with UC. In December 2018, we commenced a three-arm placebo-controlled Phase 2b clinical trial that was designed to evaluate SER-287 in approximately 201 patients with mild-to-moderate UC, termed ECO-RESET. Two groups of patients are receiving different doses of SER-287, both following pre-conditioning with a short course of oral vancomycin. A third group are receiving placebo. The study's primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Patients then enter a 26-week exploratory maintenance follow-up period. Endoscopic improvement will be measured as a secondary efficacy measure. Based on feedback from the FDA, if the data from this trial is positive, we expect that the Phase 2b clinical trial could be one of two pivotal trials to enable a BLA to be submitted for SER-287 for the treatment of UC. We anticipate top-line results in mid-2021.

The clinical development of SER-287 to treat UC, is supported by successful preclinical and clinical studies. Preclinical colitis animal models and *in vitro* screens provided evidence that SER-287 administration has the potential to reduce pathology and modulate inflammatory and immunological functional pathways. Published clinical reports also suggest that modulation of the microbiome through repetitive fecal microbiota transplantation, or FMT, may lead to meaningful clinical response in UC patients.

We completed our Phase 1b clinical study for SER-287, in subjects with active mild to moderate UC who were failing their current therapies. The results of the SER-287 Phase 1b study, a randomized, double-blinded, placebo-controlled, multiple-dose, induction study enrolled patients with active mild-to-moderate UC, with Total Modified Mayo scores of 4 to 10 were positive. The study enrolled 58 subjects who exhibited pre-study disease activity despite ongoing treatment with standard-of-care therapeutics. SER-287 safety and tolerability was a primary study endpoint. The study showed no imbalance in adverse events in SER-287-treated patients as compared to patients treated with placebo and no drug-related serious adverse events were observed.

Analyses of microbiome data, a co-primary endpoint of the trial, showed that SER-287 induced regimen-dependent engraftment of SER-287 derived bacterial species into the colonic microbiome of patients treated with SER-287. Patients administered vancomycin pre-conditioning followed by daily administration of SER-287 had the highest level of SER-287 engraftment, which was statistically significant. This patient cohort corresponded with the study arm where the most significant clinical benefits were observed, including clinical remission and endoscopic improvement. Differences in the composition of the microbiome post treatment were also associated with clinical remission. Bacterial engraftment signatures were durable throughout the dosing period of the trial and were also observed at four weeks post administration of the final SER-287 dose. The pharmacologic impact of the SER-287 engraftment was supported by metabolomic and transcriptomic data. Analysis of metabolites and gene expression signatures associated with inflammation and immune modulation, showed correlations with remission in SER-287 treated subjects. A paper titled "A Phase 1b Safety Study of SER-287, a Spore-Based Microbiome Therapeutic, For Active Mild-To-Moderate Ulcerative Colitis" was highlighted as the cover article in the January 2021 print edition of the leading journal *Gastroenterology* including data analysis on clinical remission, endoscopic improvement, modulation of the gastrointestinal microbiome, and a favorable safety profile.

We are also advancing our microbiome drug discovery and development capabilities and our next generation therapeutics, including SER-301, a therapeutic candidate for UC. SER-301 is a consortium of cultivated bacteria designed using our 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. SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF- α driven inflammation in intestinal epithelial cells, or IECs, and modulate UC-relevant anti-inflammatory, innate and adaptive immune pathways. SER-301 is being produced using our advanced fermentation, formulation and delivery platforms. It includes strains delivered in spore form, as well as strains cultivated in non-spore (vegetative) form and delivered using enterically-protected technology designed to release in the colon. In November 2020 we enrolled our first patient in the SER-301 Phase 1b study. This initial clinical study of SER-301 is being conducted in Australia and New Zealand.

SER-155 is an oral microbiome therapeutic candidate, consisting of a consortium of cultivated bacteria, that we are advancing into clinical development. 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 were significantly more likely to die due to infection and/or lethal graft versus host disease, or GvHD. SER-155 is a consortium of cultivated bacteria designed using our reverse translational discovery platform to prevent mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allo-HSCT or solid organ transplants. SER-155 is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host

immune responses to decrease GvHD. In November 2017, we were awarded a highly competitive grant from CARB-X to support continued preclinical research and early development work for SER-155. In 2019, Seres was awarded additional funding from CARB-X to support clinical development of SER-155, including support through investigational new drug application, or IND submission and Phase 1b evaluation. The 2019 CARB-X grant provides us with an additional \$4.8 million of funding for research, manufacture, and IND submission, with potential for an additional \$7.0 million for Phase 1b development, upon completion of milestones. We expect to initiate clinical development of SER-155 in the first half of 2021.

SER-401 is an oral microbiome therapeutic candidate, consisting of a consortium of purified bacteria and comprising a bacterial signature similar to that observed in checkpoint inhibitor immunotherapy responders. In March 2019, the first patient was dosed in the Phase 1b clinical study with MD Anderson and the Parker Institute, to evaluate SER-401's potential to augment the response of anti-PD-1 checkpoint inhibitor therapy. The study is designed to enroll 30 patients with metastatic melanoma who are being treated with nivolumab, an anti-PD-1 therapy. Patients are randomized at a 2-to-1 ratio to either SER-401 or placebo. The study's primary endpoints are to evaluate safety and tolerability. Its secondary endpoints are to evaluate the correlation of microbiome biomarkers of response to various clinical and immunological outcome measures.

Seres continues to monitor the impact of the COVID-19 pandemic on company operations and ongoing clinical development activity, including on the SER-401 Phase 1b study in metastatic melanoma. We are working with MD Anderson and PICI to evaluate the potential impact to the SER-401 Phase 1b readout.

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 in microbiome therapeutics, drug development, commercialization, chemistry, manufacturing and controls, or CMC, public company management and finance. Our management team has extensive experience in microbial ecology, microbiology and live biological products, with over 25 years of experience studying the microbiome and over 60 published papers on the science of the microbiome. Additionally, our team has extensive experience in building out commercial capabilities in specialty diseases and has a track record for success in the commercialization of vaccine products, which have analogous manufacturing processes to that of microbiome therapeutics.

Our Strategy

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

Advancing our Programs

- **Advancing the development of our lead product candidate, SER-109, for patients with recurrent CDI toward a BLA filing and product commercialization.** In August 2020 we reported positive topline results from the interim analysis of the pivotal Phase 3 ECOSPOR III study evaluating SER-109 for recurrent CDI. Those results showed that SER-109 administration resulted in a highly statistically significant absolute decrease of 30.2% in the proportion of patients who experienced a recurrence in CDI within eight weeks of administration versus placebo, the study's primary endpoint. At eight weeks of treatment, 11.1% of patients administered SER-109 experienced a CDI recurrence, versus 41.3% of placebo patients. The study results were equally compelling when characterized by the alternative metric of sustained clinical response, where 88.9% of patients in the SER-109 arm achieved this objective at eight weeks. Subsequent analyses from the completed Phase 3 study using the final statistically defined Intent-to-Treat population show that 12.4% of subjects experienced a recurrence, versus 39.8% on placebo which represents a relative risk of 0.32 (95% CI 0.18-0.58; $p < .001$), with an absolute risk reduction of 27% and a relative risk reduction of 69%. The percent on SER-109 with a sustained clinical response was approximately 88%. The number-needed-to-treat was 3.7. In the same updated analysis, the 12 week rate of recurrence in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65; p -value = 0.002), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study's efficacy results from all analyses exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a biological license application, or BLA. The SER-109 safety results observed to-date were favorable, with an adverse event profile comparable to placebo. We are actively enrolling patients in our SER-109 open-label study, which also admits patients with a single recurrence of CDI, to expand the safety database to meet the FDA threshold of at least 300 patients. SER-109 has been granted both Orphan

Drug and Breakthrough Therapy designation by the FDA for the treatment of CDI. Breakthrough Therapy designation provides for intensive guidance from the FDA in an effort to expedite the drug development process.

- **Continuing clinical development of SER-287 for the treatment of UC.** The clinical development of SER-287 to treat UC is supported by both clinical and preclinical studies in multiple animal models of colitis that provided evidence that SER-287 administration may result in reduced inflammation. Published clinical reports suggest that modulation of the microbiome through repetitive FMT may lead to meaningful clinical response in certain UC patients. In December 2015, we initiated a Phase 1b clinical trial evaluating SER-287 in patients with mild-to-moderate UC who were failing current therapies. In October 2017, we announced positive top-line results from our Phase 1b clinical trial of SER-287 in patients with UC. The SER-287 Phase 1b study, a randomized, double-blinded, placebo-controlled, multiple-dose, induction study enrolled patients with active mild-to-moderate UC, with Total Modified Mayo scores of 4 to 10. The study enrolled 58 patients at 20 sites across the United States. Study subjects exhibited pre-study disease activity despite use of current therapies in a majority of subjects, which included 5-amino-salicylic acid, low dose corticosteroids, or immunomodulatory therapy. Based on the encouraging data from the Phase 1b trial, in December 2018, we initiated our Phase 2b trial, ECO-RESET, evaluating SER-287 in patients with active mild-to-moderate UC. Based on feedback obtained from the FDA on the SER-287 Phase 2b study design, we believe the study, if successful, could serve as one of two required pivotal trials supporting potential future registration of SER-287. The Phase 2b study is a three-arm placebo-controlled trial of approximately 200 patients with active mild-to-moderate UC. Two groups of patients will receive different doses of SER-287, both following pre-conditioning with a short course of oral vancomycin. A third study arm will receive placebo. The study's primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Endoscopic improvement will be measured as a secondary efficacy measure. SER-287 has been granted Orphan Drug Designation for pediatric UC.
- **Developing SER-301 for the treatment of IBD.** We are developing SER-301, a microbiome therapeutic candidate comprised of a consortium of cultivated bacteria, for the treatment of IBD leveraging pharmacokinetic and pharmacodynamic data from our SER-287 clinical trial, our knowledge of modulation of the microbiome seen in patients with UC, as well as insights from our SER-262 clinical study. In November 2020 we enrolled our first patient in the SER-301 Phase 1b study. This initial clinical study of SER-301 is being conducted in Australia and New Zealand.
- **Developing SER-155 to prevent mortality from sepsis and graft-vs-host disease in patients undergoing allo-HSCT.** We have nominated the SER-155 lead candidate, a microbiome therapeutic comprised of a consortium of cultivated bacteria and are advancing the candidate into clinical development. We expect to initiate clinical development of SER-155 in the first half of 2021.
- **Developing SER-401 for use with CPIs in patients with solid tumors.** We are developing SER-401 for administration in combination with CPI treatment to increase efficacy in patients with solid tumors. The design is being driven by insights from our collaborators at MD Anderson and recent published data in a number of high-profile scientific journals from other international research groups that suggest that the microbiome may impact patients' response to CPI treatment. Together with our collaborators, we have initiated a Phase 1b multicenter study in metastatic melanoma patients as part of our collaboration with MD Anderson and the Parker Institute.

Advancing Our Capabilities

- **Leveraging our leading reverse translation 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 and of the production of microbial strains provides us a competitive advantage in the design and development of microbiome therapeutics. Our platform enables us to build upon our existing and growing clinical experience to rationally 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 microbiome therapeutics platform which we believe enables us to apply our capabilities to efficiently identify, manufacture and develop novel microbiome therapeutics for serious human diseases. We use a reverse translational discovery platform that incorporates analysis of microbiome biomarkers from human clinical data and preclinical

assessments using human cell-based assays and *in vitro/ex vivo* and *in vivo* disease models. Specifically, we start with data sets from both healthy subjects and subjects with disease to delineate at high-resolution the composition of the microbiome and physiological state of subjects and to identify specific microbiome and host signatures that associate with disease or the onset of disease. These in-human insights 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 identify at high-resolution, specific groups, species and strains of microbes as well as microbe-associated metabolites that are associated with disease states. These microbiome biomarkers are associated with host signatures and biomarkers of disease to identify disease targets for our microbiome therapeutics. Our clinical data from the SER-109, SER-262 and SER-287 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 suite of assays and bioinformatics and computational tools, 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.

Our proprietary strain library of bacterial isolates from healthy donors and patients enables us to translate microbiome biomarker insights into defined consortia of bacteria. The strain library contains bacterial species isolated from individuals that are either healthy or that have a disease. Seres has developed extensive isolation and cultivation know-how. The strain library contains a majority of the Human Microbiome Project's "most wanted" and many novel species not 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 this may impact immune responses.

We select bacteria from our library with specific predicted properties using novel algorithms for *in silico* functional design 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" mice that possess only bacteria derived from humans; these models were developed to minimize confounding variables presented by murine microbes. Data from our *in vitro/ex vivo* and *in vivo* screens are analyzed and used to optimize compositional designs; introducing new bacterial strains and optimizing existing strains until we identify a lead composition suitable for clinical testing.

Finally, we manufacture the bacterial composition under current Good Manufacturing Practices, or cGMP, 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 continue working to address quality control requirements for our microbiome therapeutic candidates using proprietary microbiological and sequence-based testing schemes, including high-throughput quantitative analytics to assess the identity, potency, and purity of the final product. We intend to work with regulators to meet the requirements for product approval.

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

Disease Overview and Our Product Pipeline

We believe our microbiome therapeutic candidates represent a novel approach with potential application across a broad range of human diseases. Our most advanced drug development program, SER-109, focuses on recurrent CDI. SER-109 has successfully completed a Phase 3 study and the product candidate has been designated as a Breakthrough Therapy and an Orphan Drug by the FDA for the treatment of CDI. We are actively enrolling patients in our SER-109 open-label study, which also is enrolling patients with

either a single or multiple recurrence of CDI, to expand the safety database to meet the FDA specified threshold of at least 300 patients. SER-287 is being evaluated in a Phase 2 study for the treatment of active mild-to-moderate UC and has completed a Phase 1b study in the United States. SER-287 has been designated an Orphan Drug for pediatric UC by the FDA. We have designed SER-301, a microbiome therapeutic candidate comprised of a consortium of cultivated bacteria, for the treatment of UC. We are advancing SER-155 into clinical developments, and we are designing SER-401 for combination therapy with immune CPIs in cancer. We have also conducted early stage research on potential microbiome therapeutic candidates for the treatment of metabolic disorders, such as early-stage, non-insulin dependent diabetes, NASH, and metabolic syndrome. Research in these indications is focused on developing drugs that address specific functional defects in the microbiome, including the specific metabolic products made by the microbes. We believe this approach may enable pursuit of a range of disorders including various forms of liver disease and rare genetic diseases of metabolism.

CDI Overview and SER-109

Clostridioides difficile Infection

C. difficile is a Gram-positive, toxin-producing, spore forming bacterium that may cause debilitating diarrhea in infected individuals, but can also lead to more severe outcomes, such as inflammation of the colon, or colitis, toxic megacolon and death. *C. difficile* bacteria express toxins that disrupt the structural architecture of cells causing leakage of fluids through the 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 US, with long-term care facilities specifically having some of the highest CDI rates. 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. There are approximately 453,000 cases of primary CDI within the United States each year and approximately 170,000 incidences of recurrent CDI. 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*). Based on an epidemiological study conducted by the CDC, the incidence of CDI in the United States, based on a positive toxin or molecular assay in patients who did not have a positive result in the previous 8 weeks, was estimated to be 453,000 (95% confidence interval, 397,100 to 508,500) (Lessa et. al., *Burden of Clostridium difficile Infection in the United States*, *New England J. of Medicine*, 2015).

Current and developing treatment alternatives and their limitations

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

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

Antibiotics have two major limitations: they have no effect on the spores that germinate in a disrupted microbiome and their use appears to exacerbate microbiome disruption, resulting in increased risk of future CDI. Research in animal models has shown that antibiotic use not only eliminates many healthy bacteria in the GI tract, but also leads to the release of nutrients that facilitate the growth of *C. difficile*. Antibiotics have also been shown to change the ratio of primary versus secondary bile acids in the colon by killing bacteria required to metabolize bile acids. This shift to a predominance of primary bile acids further facilitates the growth of *C.*

difficile, as it requires primary bile acids for germination of its spores. As a result, antibiotic use may induce a lasting microbiome disruption that makes it possible for *C. difficile* to colonize a person and then cause, or further perpetuate, disease.

Fecal microbiota transplantation. FMT, also known as a stool transplantation, is an unapproved procedure during which donated stool, including fecal microbes, is typically instilled via colonoscopy into a patient with CDI. FMT presents several challenges for effective treatment of the disease. FMT has the potential to transmit infectious or allergenic agents between hosts, involves the transmission of hundreds of unknown strains of bacteria, fungi, viruses and potentially parasites from donor to subject, and is difficult to perform on a mass scale. In November 2019 the FDA held a public hearing to obtain input on the use of FMT to treat *Clostridioides difficile* infection not responsive to standard therapies. Presentations were made by the academic community and development companies regarding the current and future use of FMT. In January, 2020, we submitted comments to the docket for the meeting that recommended: 1) increased scrutiny and regulation of unapproved, commercially available FMT that does not comply with IND requirements; 2) implementation of guidance for establishing safety of source materials for all microbiome products; and 3) safety and efficacy of all microbiome products to reduce recurrent CDI must be based on adequate and well controlled clinical trials including accurate assurance of diagnosis of the disease state – specifically toxin testing.

Additionally, FMT is inherently non-standardized so that different desired and/or undesired material may be transmitted in any given donation. FMT is not approved by the FDA and we believe that, as currently practiced by clinical centers in the United States, it may be unable to gain such approval since the product, to our knowledge, cannot be characterized according to current regulatory requirements for identity, potency, purity and safety and has not been tested in rigorous, placebo controlled, randomized and blinded clinical studies. Commercial providers of FMT must meet FDA regulatory requirements for a biologics license and must produce FMT material using cGMP.

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. The antibody demonstrated 10% absolute risk reduction in preventing recurrence of CDI. Antibodies bind toxins to alleviate the symptoms of CDI, but they do not address the underlying disruption of the microbiome, which we believe is the cause of recurrent CDI. Bezlotoxumab requires intravenous infusion.

SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores from healthy screened donors. SER-109 is designed to prevent further recurrences of CDI in patients with a history of multiple infections by restructuring the disrupted microbiome to a state that resists *C. difficile* colonization and growth. SER-109, if approved, is intended to treat individuals with recurrent CDI, a patient population which includes approximately 170,000 individuals per year in the United States. We completed enrollment with 182 patients with multiply recurrent CDI in ECOSPOR III. All patients who entered ECOSPOR III were required to 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 of comparing the *C. difficile* recurrence rate in subjects who receive SER-109 versus placebo at up to eight weeks after dosing. The SER-109 manufacturing purification process is designed to remove unwanted microbes thereby reducing the risk of pathogen transmission beyond donor screening alone.

In August 2020, we reported positive topline results from the interim analysis of the pivotal Phase 3 ECOSPOR III study evaluating SER-109 for recurrent CDI. Those results showed that SER-109 administration resulted in a highly statistically significant absolute decrease of 30.2% in the proportion of patients who experienced a recurrence in CDI within eight weeks of administration versus placebo, the study's primary endpoint, and which remained consistent at 12-weeks end point with a 31.1% absolute decrease. At eight weeks of treatment, 11.1% of patients administered SER-109 experienced a CDI recurrence, versus 41.3% of placebo patients. The study results were equally compelling when characterized by the alternative metric of sustained clinical response, where 88.9% of patients in the SER-109 arm achieved this objective at eight weeks. Subsequent analyses from the completed Phase 3 study using the final statistically defined Intent-to-Treat population show that 12.4% of subjects experienced a recurrence, versus 39.8% on placebo, which represents a relative risk of 0.32 (95% CI .018-0.58; $p < .001$), with an absolute risk reduction of 27% and an relative risk reduction of 69%. The percent on SER-109 with a sustained clinical response was approximately 88%. The number-needed-to treat was 3.7. In the same updated analysis the 12 week rate of recurrence in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65; p -value = 0.002), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study's efficacy results from all analyses exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a biological license application, or BLA. The efficacy remained durable through twenty-four weeks of follow-up.

The SER-109 safety results observed to-date were favorable, with an adverse event profile comparable to placebo. We are actively enrolling patients in our SER-109 open-label study, which is enrolling patients with single or multiple recurrences of CDI, to expand the safety database to meet the FDA threshold of at least 300 patients.

Phase 1b/2 clinical study design

The Phase 1b/2 clinical study was a two-part trial designed to evaluate the safety and efficacy of SER-109 in 30 patients with recurrent CDI. Part 1 of the study evaluated a single dose of SER-109 administered orally in 30 capsules over two days, with a dose that varied between 3×10^7 and 2×10^{10} spores. Part 2 of the study evaluated a single dose of SER-109 administered orally in a range of one to 7 capsules over one day. The target dose in Part 2 was 1×10^8 spores per dose, which was approximately 17-fold lower than the mean dose in Part 1.

Phase 1b/2 clinical study results

The primary efficacy measure was the absence of CDI (defined in this study as more than three unformed bowel movements in a 24-hour period with laboratory confirmation of a positive *C. difficile* stool test) during the eight weeks after initiating therapy. Twenty-six of 30 patients, or 87% of patients, in the Phase 1b/2 clinical study achieved the primary efficacy endpoint, consisting of 13 patients in each of Part 1 and Part 2 of the study. Among the 26 patients was one patient who experienced an initial recurrence on Day 26 and was re-treated, per protocol, with a dose from the same donor. Following re-treatment, this patient also achieved the primary efficacy endpoint. Of the patients who did not meet the primary efficacy endpoint, one had a recurrence of CDI on Day 5 and did not receive a second treatment with SER-109 and the three other patients were determined by their attending investigator to be recovering from their diarrheal episode by the time they submitted their stool sample for CDI testing. The three patients were determined to be clinically CDI free at eight weeks. As a result, the clinical cure rate for the study, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing, was 97%, or 29 of 30 patients. SER-109 was observed to be well tolerated in this study. The most common AEs were diarrhea, nausea, and abdominal pain. The majority of TEAEs were mild in severity and consistent with post-antibiotic recovery from CDI.

Phase 2 clinical study design

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. Subjects were randomized at a 2:1 ratio with 59 subjects receiving SER-109 and 30 subjects receiving placebo. SER-109 was administered orally as a single dose of 10^8 bacterial spores, following the completion of antibiotic treatment for CDI. The study was conducted at 36 centers across the United States. The primary endpoint was the absence of recurrence of *C. difficile* positive diarrhea requiring antibiotic treatment up to 8 weeks following treatment with SER-109 or placebo.

Phase 2 clinical study results

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 (25% vs 14%), abdominal pain (22% vs 14%), flatulence (12% vs 3%), and nausea (10% vs 10%), for SER-109 and placebo, respectively. No drug-related SAEs were observed. The SER-109 analyses were shared with the FDA. Based on feedback received from the FDA, a new Phase 3 SER-109 clinical study in patients with multiply recurrent CDI was initiated. Study participants were randomized 1:1 between SER-109 and placebo and received a total dose that is approximately 10-fold higher than in the Phase 2 study, administered over three consecutive days. Diagnosis of CDI for both study entry and for endpoint analysis was confirmed by *C. difficile* cytotoxin assay, compared to the first Phase 2, where most patients were diagnosed by polymerase chain reaction, or PCR.

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. This root-cause investigation looked at the clinical trial population, study conduct, and diagnostic testing used for study inclusion and endpoint analysis, assessed clinical specimens for genomic and metabolomic biomarkers that might give insight into SER-109 efficacy and potency, reviewed manufacturing procedures

and processes, performed retrospective analysis using high-resolution whole metagenomics sequencing of Phase 1b/2 clinical study stool samples, and reviewed analytical methods, that may have differed between the Phase 1b/2 and Phase 2 clinical studies. We identified key factors that potentially explain the Phase 2 clinical study results, including issues related to both the accurate diagnosis of *C. difficile* recurrent infection, and potential suboptimal dosing of subjects in the trial.

The key factors include:

- The diagnostic test for entry may not have differentiated subjects with active CDI disease from those with other disease but who had *C. difficile* carriage (e.g., irritable bowel syndrome);
- The diagnostic test for CDI recurrence during the study (the primary endpoint) overestimated recurrences, as PCR was the most common test performed;
- The safety profile of SER-109, which may include diarrhea in the first week following dosing, led to SER-109 subjects presenting for evaluation of recurrence at a time when they were likely to be colonized with *C. difficile* leading to mistaken diagnosis of recurrent CDI; and
- The dose and dosing regimen used in the study may not have been optimal in the Phase 2 clinical study based upon an assessment of the microbiome response using whole metagenomics shotgun sequencing.

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

Phase 3 clinical study design

In June 2017 we initiated a Phase 3 clinical study of SER-109 in patients with multiply recurrent CDI. Study participants were randomized 1:1 between SER-109 and placebo. Diagnosis of CDI for both study entry and for endpoint analysis utilizes 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 versus 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. The analysis reported in August 2020 on the dataset locked for the interim analysis showed that SER-109 administration resulted in a highly statistically significant absolute decrease of 30.2% in the proportion of patients who experienced a recurrence in CDI within eight weeks of administration versus placebo, the study’s primary endpoint, and which remained consistent at 12-weeks end point with a 31.1% absolute decrease. At eight weeks of treatment, 11.1% of patients administered SER-109 experienced a CDI recurrence, versus 41.3% of placebo patients. The study results were equally compelling when characterized by the alternative metric of sustained clinical response, where 88.9% of patients in the SER-109 arm achieved this objective at eight weeks. Subsequent analyses from the completed Phase 3 study using the final statistically defined Intent-to-Treat population show that 12.4% of subjects experienced a recurrence, versus 39.8% on placebo, which represents a relative risk of 0.32 (95% CI 0.18-0.58; $p < .001$), with an absolute risk reduction of 27% and a relative risk reduction of 69%. The percent on SER-109 with a sustained clinical response was approximately 88%. The number-needed-to treat was 3.7. In the same updated analysis, the 12 week rate of recurrence in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65; p -value = 0.002), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study’s efficacy results related to the primary endpoint from all analyses exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a biological license application, or BLA. The efficacy remained durable through twenty-four weeks of follow-up.

The SER-109 safety results observed to-date were favorable. SER-109 was well-tolerated through week 8, with a safety profile comparable to placebo. There was no clinically meaningful imbalance in incidence of adverse events between SER-109 and placebo arms. 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 related serious treatment-related adverse events and no treatment related infections. The most commonly observed TEAEs were gastrointestinal disorders, the majority of which were mild to moderate in nature.

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

SER-109 administration also resulted in modulation of the gastrointestinal metabolic landscape. Notably, data demonstrated a significant decrease in primary bile acids ($p = 0.038$) and an increase in secondary bile acids ($p < 0.001$) by one-week post-dosing; significant differences were maintained through week eight for secondary bile acids. Notably, SER-109 subjects had less variance across subjects in bile acid response than placebo subjects. Observations for both primary and secondary bile acids were maintained in predefined subpopulation analyses of age and antibiotic use. All microbiome analyses were conducted according to the treatment subjects actually received. Published research as well as preclinical studies have demonstrated that primary bile acids support germination of *C. difficile* spores that are the source of disease recurrence. In contrast, secondary bile acids have been reported to inhibit germination and the growth of *C. difficile* (Theriot and Young, *Annu. Rev. Microbiol.* 2015).

Manufacturing.

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

Donors are required to be in good health, and to possess a medical history that minimizes the risk of exposure to and transmission of an infectious disease. Donors are tested for infectious agents and screened for GI and other health factors. Donors are monitored for health status changes during the donation period. At the end of the donation period, the qualification assessment is repeated to help ensure the donor has maintained their health status. After successful completion of an exit screening, donations are released for use in manufacturing.

We initially process the donor material in a Cambridge manufacturing facility, and then transfer the process intermediate to a contract manufacturing organization, or CMO, to isolate and concentrate SER-109 for finishing to the oral capsule dosage form. The purified drug substance is tested for identity, potency and purity, and subsequently formulated into drug product where it is again tested for identity, potency, purity, and pharmaceutical properties. The final drug product dosage form is four hard 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 hypothetical extraneous pathogens of concern, and we believe we have sufficient data from these studies to support ongoing and proposed clinical trials.

We believe we can address market demand with a relatively small-scale manufacturing process. If approved, we anticipate that we will be able to produce a sufficient commercial supply of SER-109 to meet estimated demand in the United States using donations from a modest number of donors.

Ulcerative Colitis, SER-287 and SER-301

UC 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. As the disease mostly affects young and middle-aged individuals, a time of peak reproductive and economic productivity, the disease leads to decreased quality of life in those affected by the condition, high morbidity, and significant health economic burden. (Ghosh and Mitchell, 2007; Kappelman et al., 2008; Rubin et al., 2014; Theede et al., 2015) The incidence of UC is rising worldwide, and the prevalence of the disease is highest in the United States, Canada, and Europe. In the United States alone, the prevalence of UC in adults is estimated to be 263 per 100,000, while in the pediatric population (age <20 years), prevalence of the disease is estimated to be 33.9 per 100,000. (Kappelman et al., 2013)

UC is characterized by recurring episodes of inflammation limited to the mucosal layer of the colon. The severity of symptoms, diarrhea associated with blood and abdominal pain, may range from mild disease to severe disease with more than 10 stools per day with severe cramps and continuous bleeding. 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.

The pathogenesis of UC is unclear but thought to arise from an aberrant immune response to a change in the colonic environment in a genetically susceptible individual. The key features of UC include diffuse mucosal inflammation in a continuous pattern starting distally in the rectum to more proximal disease in the left colon to pancolitis.

Symptoms of UC include rectal bleeding, tenesmus, increased stool frequency, urgency, incontinence, fever, fatigue and malaise, which negatively impact quality of life, physical and mental health and productivity. A subset of patients has extra-intestinal manifestations ranging from iron deficiency anemia to primary sclerosing cholangitis with implications for increased morbidity. In pediatric patients, the symptoms of UC have a more damaging impact, as they affect children's growth and lead to delayed puberty. These patients also suffer from weight loss, anemia and joint symptoms and current therapy itself adversely impacts normal growth and development. (Kelsen et al., 2008). Treatment of UC with corticosteroids and immunosuppressive agents adds further medical complications to these vulnerable patients, including corticosteroid toxicity and increased risk of invasive infections and malignancy. Both environmental and genetic factors contribute to the etiology of the disease. Environmental factors may induce an ongoing immune response and inflammation in the genetically predisposed host. Efforts to identify specific environmental factors has implicated commensal bacteria or their products as key determinants of the inflammatory response in UC patients (Xavier et al., 2007). Thus, we believe SER-287 may target an "underlying cause" of UC rather than its symptoms.

Current and developing treatment alternatives and their limitations

Currently, patients with UC require life-long therapy. The goals of medical therapy are to induce and maintain clinical and endoscopic remission. Endoscopic remission is recognized as a key treatment goal since it better predicts short- and long-term clinical outcomes than symptomatic improvement alone. Attainment of these goals is generally associated with improved quality of life and decreased need for corticosteroids, and lower risk of hospitalization, colectomy, and colon cancer.

Although the etiology of UC is not fully understood, much progress has been made in the understanding of pathogenesis. Under homeostatic conditions, there is a balance between pro-inflammatory and anti-inflammatory cytokine signals mediated by epithelial and immune cells in the gastrointestinal tract. However, UC is characterized by dysregulated mucosal immune responses and translocation of inflammatory mediators of microbiological origin across a disrupted gastrointestinal barrier that may cause or perpetuate inflammation leading to chronic inflammatory disease. Migration of innate and adaptive immune cells into gut mucosal tissues is potentiated by locally produced cytokines and chemokines, and by the expression of integrins that enhance cellular trafficking into the gut lamina propria. Inhibition of the immune response, via antibodies and proteins that sequester pro-inflammatory cytokines or block the function of integrins, has been an important target of UC drug development over the past decade.

Management of UC includes medications that decrease general inflammation (e.g., 5-aminosalicylate derivatives, or 5-ASA, corticosteroids) or dampen specific components of the host immune response (e.g., immunomodulators, inhibitors of tumor necrosis factor, anti-integrin antibodies).

For mild-to-moderate disease, the 5-ASA derivatives are the standard of care for both induction and remission. 5-ASA derivatives achieve clinical remission in only 25-40% of patients during induction and approximately one-third of responders have disease flares during the first year of maintenance therapy, necessitating additional treatment interventions such as corticosteroids and immunomodulators (e.g. 6-mercaptopurine, methotrexate, azathioprine). Corticosteroids are not recommended by guideline panels for chronic therapy since these drugs are ineffective for maintaining remission and are associated with significant adverse events. Patients taking thiopurines require ongoing monitoring for hepatotoxicity, myelosuppression, and opportunistic infections, as well as counseling on the potential risk of lymphoma.

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

SER-287

Given the modulation of the microbiome seen in UC patients, studies have explored the use of FMT to treat UC. (Angelberger et al., 2013; Colman and Rubin, 2014; Kump et al., 2013; Kunde et al., 2013; Moayyedi et al., 2015; Paramsothy et al., 2017; Costello SP et al JAMA 2019). Early reports of enhanced clinical remission and endoscopic improvement with repetitive FMT compared to placebo motivated the preclinical development and clinical testing of SER-287.

SER-287, an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicute spores, is designed to normalize the gastrointestinal microbiome of individuals with UC. In December 2018, we commenced a three-arm placebo-controlled Phase 2b clinical trial that was designed to evaluate SER-287 in approximately 201 patients with mild-to-moderate UC. Two groups of patients are receiving different doses of SER-287, both following pre-conditioning with a short course of oral vancomycin. A third study arm will receive placebo. The study's primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Patients then enter a 2-week exploratory maintenance follow-up period. Endoscopic improvement will be measured as a secondary efficacy measure. Based on feedback from the FDA, if the data from this trial is positive, we expect that the Phase 2b clinical trial could be one of two pivotal trials to enable a BLA to be submitted for SER-287 for the treatment of UC.

There are approximately 700,000 UC patients in the United States and fewer than one-third of patients on current therapies achieve remission. Approved treatments are often inadequate to control disease activity and are often associated with significant side effects, including immunosuppression. We believe that SER-287 may address underlying drivers of inflammation in UC and, based on the favorable tolerability profile observed in our clinical trials of SER-287, we believe has the potential to be developed as both a foundational monotherapy, as well as a combination therapy with other UC drugs. SER-287 has been granted Fast Track Designation by the FDA for the induction and maintenance of clinical remission in adult subjects with active mild-to-moderate UC. SER-287 has been designated an Orphan Drug for pediatric UC by the FDA.

Further details of Phase 1b clinical study design

The Phase 1b clinical study was a multicenter, randomized, double-blind, placebo-controlled multiple dose study utilizing weekly or daily dosing with SER-287. We enrolled eligible subjects at approximately 20 sites in the United States. The Phase 1b clinical study was designed to enroll adults 18 years of age and older who had mild-to-moderate UC as defined by a Total Modified Mayo score between 4 and 10, inclusive, with a modified Mayo endoscopic subscore ≥ 1 , who were failing current therapies.

Patients were randomized to one of four study arms:

- Pre-conditioning with placebo for 6 days, followed by weekly dosing of SER-287 for 8 weeks
- Pre-conditioning with placebo for 6 days, followed by daily dosing with placebo for 8 weeks
- Pre-conditioning with vancomycin for 6 days, followed by daily dosing of SER-287 for 8 weeks
- Pre-conditioning with vancomycin for 6 days, followed by weekly dosing of SER-287 for 8 weeks

The primary objectives of the study were to evaluate the safety and tolerability of SER-287 compared to placebo; to compare the baseline composition of the intestinal microbiome to the composition at 8 weeks post-initiation of SER-287 or placebo; and to determine the engraftment of SER-287 bacteria into the intestinal microbial community in each of the SER-287 arms compared to the placebo arm.

The secondary objectives of the study were to determine the proportion of subjects in each of the treatment arms who at eight weeks post-initiation of treatment achieve a clinical response, complete remission, and endoscopic improvement; to assess changes in serum and fecal biomarkers from baseline throughout treatment; to determine the complement of metabolic pathways; and to compare the changes in exploratory biomarkers from mucosal biopsies and stool in each of the treatment arms from baseline through eight weeks.

This study was designed to provide evidence of safety of SER-287 compared to placebo for the UC population, describe the changes in the microbiome as a result of treatment with SER-287 and provide potential predictive biomarkers for future studies. UC is characterized by a decrease in microbial diversity and richness, with a lower prevalence of spore-forming organisms within the phylum Firmicutes. Preliminary data using repetitive enema FMT suggest that microbial interventions can affect clinical outcomes in UC, and this study evaluated whether the ecology of bacterial spores in SER-287 could correct the modulation of the microbiome in UC, increase microbial diversity and safely lead to a clinical response in UC patients with mild-to-moderate disease.

Phase 1b clinical study results

Results were analyzed using the intent to treat, or ITT, "missing equals failure" analysis and the ITT "observed case" analysis methods. The ITT "missing equals failure" analysis, included all 58 randomized subjects. For this analysis, incalculable clinical endpoints due to missing data, UC medication added due to UC flare during the treatment period and discontinuation from the trial prior to Day 48 were considered as not achieving the clinical endpoints (worst outcome). However, if the end-of-trial endoscopy at Day 48, or later, was available, and the subject did not take additional UC medication due to UC flare, then the observed data was used to define success or failure for the subject. A period of 48 days of microbiome therapy was considered sufficient treatment to estimate the outcome of clinical endpoints and was prespecified. The ITT "observed case" analysis included 53 of 58 subjects randomized, excluding those who were missing their end-of-treatment endoscopies and used the observed data to define success or

failure for each subject in the analysis. A paper titled “A Phase 1b Safety Study of SER-287, a Spore-Based Microbiome Therapeutic, For Active Mild-To-Moderate Ulcerative Colitis” was published as the highlighted over article in the January 2021 print edition of the leading journal *Gastroenterology* including data analysis from the Phase 1b trial of Ser-287 demonstrating that SER-287 administration was associated with positive impacts on clinical remission, endoscopic improvement, modulation of the gastrointestinal microbiome, and a favorable safety profile.

Clinical efficacy results

In the “missing equals failure” analysis, remission showed a statistically significant improvement in the vancomycin pre-conditioning / SER-287 once-daily dosing arm as compared to the placebo/placebo daily arm: 40% (6 of 15 in SER-287) vs 0% (0 of 11 in placebo); change from placebo of 40.0% (95% confidence interval: 15.2%, 64.8%), (p-value, 0.0237). (See Figure 1).

The SER-287 weekly treatment arms also showed an improvement over placebo in both remission and endoscopic improvement but the effect was less than with the daily dosing regimen, showing a dose-response to SER-287 in these efficacy endpoints. Addition of vancomycin to the SER-287 weekly dosing regimen did not clearly alter efficacy results, although we believe this may be due to the small size of the study.

Clinical response (data not shown), showed a numeric increase in the vancomycin/SER287 daily treatment arm compared to placebo but did not reach statistical significance.

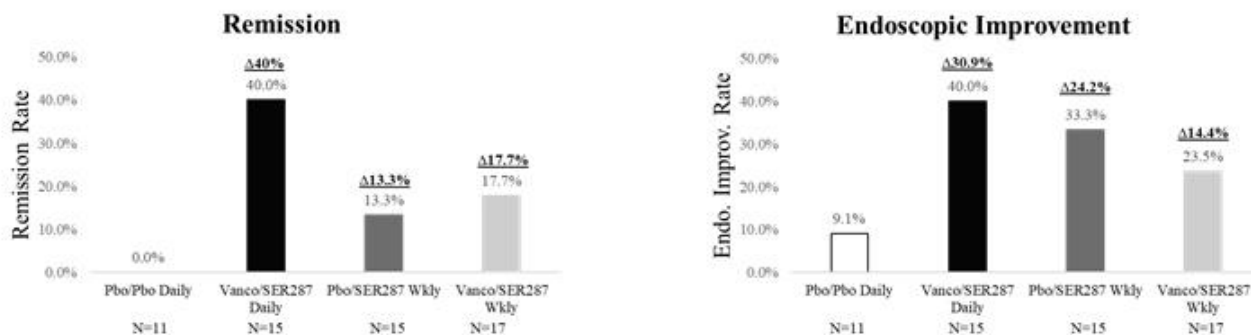


Figure 1: SER-287 Phase 1b Clinical Study Efficacy Data – Missing Equals Failure

Legend: Δ = change from placebo; Remission was defined as a Total Modified Mayo score of less than or equal to 2, and an endoscopic sub-score of 0 or 1; Endoscopic improvement was defined as a decrease in endoscopic sub score of greater than or equal to 1. Endoscopy measures were analyzed by a Central Reader.

Clinical Safety Results

The primary safety objective (short-term safety) was to evaluate the safety and tolerability of SER-287 in adults with active mild-to-moderate UC up to 92 days after randomization as determined by clinical and laboratory safety assessments.

The treatment-emergent adverse events, or TEAEs, were balanced across all the treatment arms. No drug-related serious adverse events, or SAEs, were reported. All adverse events, or AEs, were considered mild to moderate in intensity. Gastrointestinal, or GI, disorders had the greatest number of AEs compared to other system organ classes, with the most efficacious treatment arm (vancomycin/SER-287 daily) experiencing the lowest percentage of GI AEs.

SER-287 was observed to be well-tolerated in all treatment arms, showing a safety profile consistent with the placebo arm. The safety profile, when evaluating GI AEs, showed an improvement in the vancomycin/SER-287 treatment arm compared to vancomycin/placebo and the vancomycin/SER-287 weekly treatment arms.

A paper titled “A Phase 1b Safety Study of SER-287, a Spore-Based Microbiome Therapeutic, For Active Mild-To-Moderate Ulcerative Colitis” was published as the highlighted over article in the January 2021 print edition of the leading journal *Gastroenterology* including data analysis from the Phase 1b trial of Ser-287 demonstrating that SER-287 administration was associated with positive impacts on clinical remission, endoscopic improvement, modulation of the gastrointestinal microbiome, and a favorable tolerability profile

Microbiome results showed engraftment of SER-287-derived bacterial species in patients pre-conditioned with vancomycin who received SER-287. The degree of SER-287 engraftment, as measured by the number of detectable SER-287-derived bacterial species, increased in a dose-dependent manner, with daily dosing providing the most rapid and robust change in patients' microbiome. Engraftment was maintained during the entire dosing period and was observed four weeks after the last dose of SER-287 was administered. Thus, engraftment was durable. Changes in the composition of the GI microbiome were associated with clinical remission and further associated with changes in stool metabolite and intestinal biopsy gene expression signatures associated with inflammation and immune modulation. Vancomycin pre-conditioning, as compared to placebo pre-conditioning, led to an immediate reduction of microbiome diversity followed by rapid and robust engraftment of SER-287-derived bacterial species. These data suggest that vancomycin pre-conditioning opens ecological niches for SER-287 engraftment in the human microbiome of patients with UC.

Phase 2b clinical study design

Based on feedback from the FDA, we believe that the results from the SER-287 Phase 2b ECO-RESET study in conjunction with data from a second pivotal study designed to also evaluate maintenance, could enable submission of a SER-287 Biologics License Application.

The Phase 2b study, initiated in December 2018, is a three-arm placebo-controlled trial of approximately 200 patients with active mild-to-moderate UC. Two groups of patients will receive different doses of SER-287, both following pre-conditioning with a short course of oral vancomycin. A third study arm will receive placebo. The study's primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Endoscopic improvement will be measured as a secondary efficacy measure.

SER-301

SER-301, is an investigational, oral, microbiome therapeutic candidate comprised of a consortium of cultivated bacteria for the treatment of mild-to-moderate ulcerative colitis (UC). SER-301 is a consortium of cultivated bacteria designed using our 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. SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF- α driven inflammation in IECs, and modulate UC-relevant anti-inflammatory, innate and adaptive immune pathways. SER-301 is being produced by our advanced fermentation, formulation and delivery platforms. It includes strains delivered in spore form, as well as strains fermented in non-spore (vegetative) form and delivered using enterically-protected technology designed to release in the colon.

Phase 1b clinical study design.

The SER-301 Phase 1b study is being conducted in Australia and New Zealand in subjects with mild-to-moderate UC and is designed to include approximately 65 patients distributed across two cohorts. A first open-label cohort of 15 subjects will evaluate safety and pharmacokinetics (PK), as measured by bacterial engraftment. In the second cohort, 50 subjects will be randomized to receive either SER-301 or placebo, with a 3:2 randomization, respectively. The study utilizes an independent blinded central reader for the endoscopic component. The objectives for this cohort are to evaluate safety and PK, clinical remission, and other measures of drug pharmacology and efficacy will be evaluated as secondary endpoints.

Other Programs

SER-155

SER-155, an oral consortium of cultivated bacteria is a microbiome therapeutic candidate that we are advancing into clinical development. The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan Kettering Cancer Center showing that allo-HSCT patients with decreased diversity of commensal microbes are significantly more likely to die due to infection and/or lethal graft versus host disease, or GvHD. SER-155 is consortia of cultivated bacteria designed using our reverse translational discovery platform to prevent mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation (allo-HSCT) or solid organ transplants. SER-155 is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. In November 2017, we were awarded a highly competitive grant from CARB-X to support continued preclinical research and early development work for SER-155. In 2019, Seres was awarded additional funding from CARB-X to support clinical development of SER-155, including support through IND filing and Phase 1b evaluation. The 2019 CARB-X grant provides us with an additional \$4.8 million of funding for research, manufacture, and IND submission, with potential for an additional \$7.0 million for Phase 1b development, upon completion of milestones. We expect to initiate clinical development of SER-155 in the first half of 2021.

SER-401

We are also developing SER-401, for use with CPIs in patients with solid tumors to enhance efficacy and improve survival. SER-401, an oral consortium of purified bacteria is a microbiome therapeutic candidate comprising a bacterial signature similar to that observed in checkpoint inhibitor immunotherapy responders. In March 2019, the first patient was dosed in the Phase 1b clinical study

with MD Anderson and PICI, to evaluate SER-401's potential to augment the response of anti-PD-1 checkpoint inhibitor therapy. The study is designed to enroll 30 patients with metastatic melanoma who are being treated with nivolumab, an anti-PD-1 therapy. Patients are randomized at a 2-to-1 ratio to either SER-401 or placebo. The study's primary endpoints are to evaluate safety and tolerability. Its secondary endpoints are to evaluate the correlation of microbiome biomarkers of response to various clinical and immunological outcome measures.

We continue to monitor the impact of the COVID-19 pandemic on company operations and ongoing clinical development activity, including on the SER-401 Phase 1b study in metastatic melanoma. Mitigation activities to minimize COVID-19-related operation disruptions are ongoing, however, given the severity and evolving nature of the situation, the timing of the SER-401 Phase 1b clinical readout is uncertain.

Sales and Marketing

If SER-109 is approved in the United States and Canada, we believe it can be commercialized with a focused specialty sales force that will target gastrointestinal and infectious disease physicians, which are the two primary groups of physicians who treat recurrent CDI patients. In preparation for ECOSPOR III regulatory submissions, we have initiated commercial readiness activities that include: *C. difficile* market assessments, publication and presentation planning, stakeholder and advocacy relationship mapping, brand name selection, and initiation of payer and reimbursement strategic planning.

In January 2016, we entered into an agreement with Nestec Ltd., which was succeeded in interest by Société des Produits Nestlé S.A., or Nestlé, for the development and commercialization outside of the United States and Canada of our product candidates in development for CDI and IBD, including UC and Crohn's disease. The agreement will support the development of our portfolio of products for CDI and IBD in markets outside of the United States and Canada and provide financial support for our ongoing research and development.

Manufacturing

The production of live bacterial products is highly specialized. Owing to their hardiness and environmental persistence, production of spore-forming organisms poses unique considerations for product, personnel, and facility protection. Manufacturing activities with spores are subject to 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 is split between several strains, the per-strain requirements for production may be even lower. As a result, we believe the high productivity relative to the dose level will enable production scales for both clinical and commercial supply to be modest.

We have developed 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 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 originating 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. For our oral products, purification is typically less complex than for parenteral biologics such as monoclonal antibodies that must purify away very similar components from the culturing process. Separation of viable microbes from soluble fermentation broth components is typically much simpler.
- **Formulation.** Our microbiome therapeutic candidates are combinations of bacteria and can be administered by a number of methods and by different routes. 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, 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 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 and in-process analytical tools that can quantitatively measure the composition of spore, vegetative microbe and spore/vegetative combinations, which we believe enable a wide variety of drug products to be manufactured. Throughout the bioprocess and formulation development platform we use and will expand on quantitative analytics to assess the identity, potency and purity of the final product.

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

Material Agreements

Collaboration Agreements

Agreement with Nestlé

In January 2016, we entered into the Collaboration and License Agreement, or the License Agreement, with Nestec, Ltd., which was succeeded in interest by Société des Produits Nestlé S.A., or Nestlé, an affiliate of Nestlé Health Science US Holdings, Inc., both of which are significant stockholders of ours, 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. The 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 Licensed Territory. We have retained full commercial rights to our entire portfolio of product candidates with respect to the United States and Canada.

Under the License Agreement, we granted to Nestlé an exclusive, royalty-bearing license to develop and commercialize, in the Licensed Territory, certain products based on our microbiome technology that are being developed for the treatment of CDI and IBD, including SER-109, SER-262, SER-287 and SER-301, or collectively, the Nestlé Collaboration Products. The License Agreement sets forth our and Nestlé's respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the Nestlé Collaboration Products with respect to the licensed fields and the Licensed Territory.

In exchange for the license, Nestlé made an upfront cash payment to us of \$120.0 million. Nestlé also agreed to pay us tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of Nestlé Collaboration Products in the Licensed Territory. Under the License Agreement 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 \$1,125.0 million for the achievement of certain commercial milestones related to the sales of Nestlé Collaboration Products.

In November 2018, we executed a letter agreement with Nestlé, or the Letter Agreement, modifying certain terms of the License Agreement. Under the Letter Agreement, Nestlé agreed to accelerate the payment of the \$20.0 million Phase 3 commencement milestone to be payable upon the commencement of the Phase 2b study for SER-287. Further, based on the results of the Phase 2b study, the Letter Agreement modifies certain terms and conditions related to the extent and timing of expense reimbursement associated with the ongoing SER-287 clinical trials. The Phase 2b study was initiated and the \$40.0 million of milestone payments were received in December 2018.

To date, we have received \$80.0 million in development milestones under the License Agreement with Nestlé.

Agreement with AstraZeneca

In March 2019, we entered into a Research Collaboration and Option Agreement, or the Research Agreement, with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc., or AstraZeneca to conduct certain research and development activities with the goal of advancing the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy, including potential synergy with AstraZeneca compounds in accordance with a mutually agreed research plan. AstraZeneca bore all costs of conducting its activities under the Research Agreement and reimbursed us for certain of our costs incurred under the Research Agreement and paid us a total of \$20.0 million in three equal installments, the first of which we received in April 2019, the second of which we received in December 2019 and third of which we received in January 2021.

In December 2020, we received written notice from AstraZeneca that they elected to terminate the Research Agreement by and in accordance with its terms. The termination of the Research Agreement will be effective on April 2, 2021 (the “Termination Date”), which is 120 days from the date of the termination notice.

Loan and Security Agreement with Hercules

In October 2019, we entered into a loan and security agreement with Hercules, pursuant to which a term loan in an aggregate principal amount of up to \$50.0 million, or the Term Loan Facility, is available to us in three tranches. We received the first tranche of \$25.0 million upon signing the agreement on October 29, 2019. We did not meet the milestone requirements for the second tranche under the Term Loan Facility, and as such, the additional amount up to \$12.5 million is not available for us to borrow. The third tranche, which allows us to borrow an additional \$12.5 million, will be available upon Hercules’ approval on or prior to June 30, 2021.

Intellectual Property

We strive to protect the proprietary technology that is important to our business, including seeking and, if granted, maintaining patents intended to cover our product candidates and compositions, their methods of use and processes for their manufacture and any other aspects of inventions that are commercially important to the development of our business. We also utilize regulatory exclusivity as well as trade secrets to protect aspects of our business.

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

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

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

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

Patent Term

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

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

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

Trade Secrets

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

Competition

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development of products, including microbiome therapeutics, and disease indications we are targeting. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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

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

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

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

Government Regulation

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

approvals and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drug and biologic products under the Federal Food, Drug and Cosmetic Act, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates are subject to regulation by the FDA as biologics. Biologics require the submission of a biologics license application, or 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 FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the product.

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

Preclinical and Clinical Trials

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

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol must be submitted to the FDA as part of the IND. An independent institutional review board, or IRB, for each investigator site proposing to participate in a clinical trial must also review and approve the clinical trial before it can begin at that site, and the IRB must monitor the clinical trial until it is completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

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

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

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

BLA Submission and FDA Review

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

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

Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing, but the overall timeframe is often extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether the biological product is safe, pure and potent and whether the facility or facilities in which it is manufactured meet standards designed to assure the product's continued safety, purity and potency. The FDA may also refer the application to an Advisory Committee for review, evaluation, and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving a BLA, the FDA will inspect the facility or the facilities at which the biologic product is manufactured and will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure that such trials were conducted in compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter

authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new biologics designed to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review designation and Accelerated Approval, and the purpose of these programs is to expedite the development and review of qualifying product candidates.

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

In addition, a biologic product candidate may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product candidate submitted to the FDA for approval, including a product candidate with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review process, including Priority Review designation and accelerated approval. A BLA is eligible for Priority Review if the product candidate has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Additionally, product candidates are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies 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. However, complexities associated with the larger, and often more complex,

structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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

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

Orphan Drug Designation

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

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

Government Regulation Outside of the United States

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

Clinical trials

Certain countries outside of the United States have a similar process that requires the submission of a clinical study application, or CTA, much like the IND prior to the commencement of human clinical studies. In the European Union, or EU, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved by the national health authority and the ethics committee has granted a positive opinion in relation to the conduct of the trial in the relevant member state(s), in accordance with a country's requirements, clinical study development may proceed.

Clinical trials of medicinal products in the European Union must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products, or ATMPs. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal

representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. 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. Currently, CTAs must be submitted to the competent authority in each EU member state in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to take effect by early 2022, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only limited involvement. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with GMP. Other national and European Union-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 European Union, medicinal products can only be placed on the market after obtaining a Marketing Authorization, or MA. To obtain regulatory approval of an investigational biological product in the EU, we must submit a marketing authorization application, or MAA. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The process for doing this depends, among other things, on the nature of the medicinal product.

Centralized procedure—Under the centralized procedure, following the opinion of the EMA’s Committee for Medicinal Products for Human Use, or CHMP, the European Commission issues a single marketing authorization valid across the entire territory of the EU. The centralized procedure is compulsory for human medicines derived from biotechnology processes, such as genetic engineering, advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EU, is a significant therapeutic, scientific or technical innovation, or if its authorization 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 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.

National authorization procedures—There are also two other possible routes to authorize medicinal products in several countries, 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 will be 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 country. Following this, further marketing authorizations can be sought from other EU member states in a procedure whereby the countries concerned recognize the validity of the original national marketing authorization.

MAAs 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, new chemical entities (*i.e.*, reference 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 marketing authorization 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 marketing authorization 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 European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the European Union. 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 European Union are similar in principle to those in the United States. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The application for orphan drug designation must be submitted before the MAA. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a MA, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication. An orphan medicinal product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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

Pediatric Development

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

supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

Post-Approval Requirements

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

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

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization 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 EEA (comprised of the 27 EU member states plus Iceland, Liechtenstein and Norway).

Other Healthcare Laws

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

The False Claims Act, or FCA, imposes liability on persons who, among other things, knowingly present or cause to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly make a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, and has obtained multi-million and multi-billion-dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government authorities will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposed new reporting requirements through the Physician Payments Sunshine Act on certain manufacturers of drugs covered by a federal healthcare program for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals beginning in 2022 and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Manufacturers must submit reports by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians, and pricing information and marketing expenditures.

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

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. Violations of any of such laws or any other governmental regulations that apply to drug manufacturers may result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs, reporting obligations and integrity oversight, and imprisonment.

Coverage and Reimbursement

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

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

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

any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low priced markets exert a commercial pressure on pricing within a country.

Healthcare Reform

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

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

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

There have been judicial, executive and Congressional challenges to certain aspects of the ACA, as well as efforts to repeal or replace certain aspects of the ACA. For example, the Tax Cuts and Jobs Act was enacted, which, among other things, removes the penalties for not complying with the ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

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 of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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. 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. 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 or state 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 and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers’ personal information secure constitutes 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. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. In addition, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for “protected health information” maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

Human Capital

Employees

As of December 31, 2020, we had 155 full-time permanent employees. 25 employees work in administration and operations and 130 work in research and development. A portion of our personnel costs are reimbursable under our grant from CARB-X. None of our employees in the U.S. are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good. During 2020, we enhanced our capabilities by adding 55 new full-time employees. The new employees were hired to support a variety of functions and key initiatives, including extending our research, clinical and pre-clinical pipeline development, as well as our medical affairs, manufacturing and commercialization capabilities, with hires in commercial, clinical development and operations, research, medical affairs, manufacturing, and general and administrative functions. We expect to continue to add additional employees in 2021, with a focus on further enhancing our capabilities and increasing our capacities in these areas, as well as expanding our geographic reach as we continue our focus on gaining FDA approval for SER-109 for recurrent CDI.

Talent Acquisition and Development

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

Diversity, Inclusion, and Belonging

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

COVID-19 Pandemic

We are operating at a unique time, as we face a serious public safety crisis because of the COVID-19 virus. We remain focused on continuing to serve clinical trial patients, as well as protecting the health and safety of our employees and the communities in which we live and work. In early March 2020, we activated a task force designed to assess, mitigate and manage the risks related to COVID-19 to avoid or minimize business disruption, including safeguarding of our facilities, and to ensure the safety and sense of security for our staff. In early March 2020, we closed all sites to non-essential employees, and we have suspended all non-essential travel indefinitely. We continue to keep all our sites closed to non-essential employees and encourage remote working arrangements for employees. Office sites are being reconfigured to maintain physical distancing and we expect to adopt and implement additional precautions commensurate with any expansion of employees returning to worksites. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations.

Our Corporate Information

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

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

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 Securities and Exchange Commission.

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 Results of Operations and Financial Condition.” The occurrence of any of the events or developments described below or elsewhere in this report could harm our business, financial condition, results of operations or growth prospects.

Risks Related to Our Financial Position and Need for Additional Capital

We are a development-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was \$89.1 million for the year ended December 31, 2020, \$70.3 million for the year ended December 31, 2019, and \$98.9 million for the year ended December 31, 2018. As of December 31, 2020, we had an accumulated deficit of \$548.8 million. 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 not completed development of any of our product candidates, which we call microbiome therapeutic candidates, or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses may increase substantially as we:

- complete the clinical development and prepare for potential commercialization of SER-109, if approved for patients with recurrent CDI;
- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-301 for treatment of recurrent UC;
- conduct research and initiate clinical development of SER-155 for the prevention of mortality due to GvHD in immunocompromised patients receiving allo-HSCT;
- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- make strategic investments in manufacturing capabilities;
- make strategic investments in our research discovery and development platforms and capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under our agreements with our collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

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

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

Our expenses may increase in connection with our ongoing activities, particularly as we continue the clinical development of SER-109, continue the clinical development of SER-287, including conducting the Phase 2b clinical study, continue clinical studies of SER-301 and SER-401, and continue to research, develop and initiate clinical trials of SER-155 and our other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company, including as a result of no longer qualifying as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We expect that our cash, cash equivalents and investments as of December 31, 2020 will be sufficient to fund our operating expenses, debt service obligations and capital expenditure requirements for at least the next 12-months from the issuance of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In addition, the specifics of existing and future clinical trial activities could impact capital requirements and cash projections. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

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

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additionally, market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders and may decrease our stock price. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay, or discontinue one or more of our research or development programs or the commercialization of any product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

Since our inception in October 2010, we have devoted substantially all of our resources to developing our clinical and preclinical program, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our

control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

Other than SER-109 and SER-287, we are early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.

We are using our microbiome therapeutics platform to develop microbiome therapeutic candidates. We are at an early stage of development and our platform has not yet, and may never, lead to approvable or marketable drugs. We are developing additional product candidates that we intend to be used to prevent 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 preventing infection and disease. Our product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

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

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

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

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

All of our product candidates are based on microbiome therapeutics, a novel potential class of live biotherapeutic drug candidates, which are consortia of microbes designed to treat or prevent disease by modulating the microbiome through key compositional and functional changes relevant to disease outcomes. We have not, nor to our knowledge has any other company, received regulatory approval for, or manufactured on a commercial scale, a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products or that we will be able to manufacture at commercial scale, if approved. In addition, our microbiome therapeutic candidates may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of products based on microbiome therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates.

Our microbiome therapeutics platform relies on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with disease organisms,

we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our materials or products, which could delay the development or commercialization of our product candidates.

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

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

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

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

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulatory authorities or institutional review boards (or ethics committees) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- failures or delays in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may demonstrate undesirable side effects or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or institutional review boards (or ethics committees) may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regarding trials managed by any current or future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us.

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

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

For example, in March 2020, as a result of the COVID-19 pandemic, we halted further enrollment of the recently completed ECOSPOR III trial with 182 patients enrolled. Following receipt of the Phase 3 top-line data from ECOSPOR III, the FDA reaffirmed its prior position that at least 300 patients will be required for the safety database for SER-109, and we are now actively enrolling patients in our SER-109 open-label study to expand the safety database to meet this threshold. We may also be required to treat more patients with SER-109 than we currently expect before we are able to generate a safety database sufficient to allow us to seek approval of SER-109. Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the commercialization of SER-109 or otherwise adversely affect our business. In addition, prolonged disruptions caused by the COVID-19 pandemic could severely impact our preclinical studies and clinical trials, including by causing further difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. See “—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.”

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

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

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

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

Patient enrollment is also affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of other treatments for the disease under investigation, including the use of unapproved fecal microbiota transplant, or FMT, for CDI;
- 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 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.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become 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 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 from commercializing the product candidate in that jurisdiction and may affect our plans for commercialization in other jurisdictions as well. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, risky and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our microbiome therapeutic candidates. The FDA or foreign regulatory authorities may delay, limit, or deny approval to market our product candidates for many reasons, including: our inability to demonstrate that the clinical benefits of our product candidates outweigh any safety or other perceived risks; the regulatory authority's disagreement with the interpretation of data from nonclinical or clinical studies; the regulatory authority's requirement that we conduct additional preclinical studies and clinical trials; changes in marketing approval policies during the development period; changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application; or the regulatory authority's failure to approve the manufacturing processes or third-party manufacturers with which we contract. There may also be interruptions or delays in the operations of the FDA or other foreign regulatory authorities due to the COVID-19 pandemic, which may impact approval timelines. Regulatory authorities have substantial discretion in the approval process and may refuse to accept a marketing application if deficient. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

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

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

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

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

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

We may seek Fast Track designation for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for Fast Track designation. SER-287 received Fast Track designation from the FDA for the induction and maintenance of clinical remission in adults with mild-to-moderate UC. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review of a BLA for such product candidate. The FDA has broad discretion whether or not to grant this designation, and even if we believe another particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even with Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast Track designation does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

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

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

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

We have obtained orphan drug designation from the FDA for SER-109 for recurrent CDI and SER-287 for pediatric ulcerative colitis 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 indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for that time period, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure a sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity for a product may not effectively protect the product from competition because

different drugs and biologics can be approved for the same condition. Even after an orphan drug or biologic is approved, the FDA can subsequently approve the same drug or biologic for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. 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 to review and 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 ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's 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 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, including for 35 days beginning on December 22, 2018, 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 global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to our Dependence on Third Parties and Manufacturing

The Collaboration and License Agreement, or the License Agreement, with Société des Produits Nestlé S.A., or Nestlé (formerly Nestec, Ltd.), is important to our business. If we or Nestlé fail to adequately perform under the License Agreement, or if we or Nestlé terminate the License Agreement, the development and commercialization of our CDI and IBD product candidates, including SER-109, SER-287, and SER-301, would be delayed or terminated and our business would be adversely affected.

The License Agreement may be terminated:

- by Nestlé in the event of serious safety issues related to SER-109, SER-287, SER-301 or other specific products added under the License Agreement, or, collectively, the Nestlé 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 License Agreement, all licenses granted to Nestlé by us will terminate, and all rights in and to the Nestlé Collaboration Products held by Nestlé will revert to us. If we commit a material breach of the License Agreement, Nestlé may elect not to terminate the License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the License Agreement. If Nestlé were to make such adjustments, the funding from and benefits of the License Agreement could be diminished, which could adversely affect our financial condition. Unless the License Agreement is terminated by us for Nestlé's uncured material breach, upon termination of the License Agreement, Nestlé will be eligible to receive post-termination royalties from us until Nestlé has recouped certain development costs related to the Nestlé Collaboration Products and specified percentages of any milestone payments paid to us under the License Agreement prior to termination, which could have a material adverse effect on our business.

Termination of the License Agreement could cause significant delays in our product development and commercialization efforts that could prevent us from commercializing our CDI and IBD product candidates, outside of the United States and Canada, 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 License Agreement, Nestlé agreed to provide funding for certain clinical development activities. If the License Agreement were terminated, we may need to refund those payments and seek additional financing to support the research and development of any terminated products or discontinue any terminated products, which could have a material adverse effect on our business.

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

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

We expect to continue to rely on third parties, such as contract research organizations, or 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. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Other countries' regulatory authorities also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *ClinicalTrials.gov*, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

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

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of 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. The contract manufacturers we rely on to produce our product candidates have never produced an FDA-approved therapeutic. If our manufacturers are unable to comply with cGMP regulation 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 that might be capable of manufacturing our products. Therefore, our product candidates and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and commercialization of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Except for our clinical production facility in Massachusetts, we do not currently have arrangements in place for redundant supply of product. We do not currently have a second source for required materials used for the manufacture of finished product. If our current manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and commercialization efforts. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers may be affected, which could disrupt their activities and as a result we could face difficulty sourcing key components necessary to produce supply of our product candidates, which may negatively affect our preclinical and clinical development activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development of products, including microbiome therapeutics, 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 cure rates for recurrent CDI and our competitors and physicians may continue to seek to standardize and implement this procedure. Potential competitors also include academic institutions, government agencies, not-for-profits, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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

The FDA or other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA or other regulatory authorities closely regulates the post-approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDA's and regulatory authorities' restrictions relating to the promotion of prescription drugs may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

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

Noncompliance with similar 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. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders,

that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

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

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

Our relationships 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 to criminal sanctions, civil penalties, exclusion from governmental healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- the False Claims Act, imposes, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and regulations implemented thereunder, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals beginning 2022 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;
- 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; and

- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. By way of example, the CCPA, effective January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the CPRA was also recently voted into law by California residents. The CPRA significantly amends the CCPA and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect on January 1, 2023 and become enforceable on July 1, 2023. In Europe, the GDPR, which went into effect in May 2018, introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that we may violate one or more of the requirements.

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

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

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

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

Among the provisions of the ACA of importance to our potential product candidates are the following:

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

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

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, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. 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. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain.

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

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA

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

Risks Related to Our Intellectual Property

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

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

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. Prosecution of our patent portfolio is at a very early stage. For some patent applications in our portfolio, we have filed national stage applications based on our Patent Cooperation Treaty, or PCT, applications, thereby limiting the jurisdictions in which we can pursue patent protection for the various inventions claimed in those applications. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

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

We currently have, and may have in the future, certain funding arrangements, such as our grant from CARB-X to support certain work for SER-155. 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. In addition, under our CARB-X grant, we may be required in the future to grant a private sector charitable organization a license to certain of our intellectual property related to the subject matter of the CARB-X grant if, after a certain period of time, we are not developing and have not licensed a third party to develop the applicable technology for certain indications in a given country, and the organization wishes to do so. 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 23 active patent application families (which includes an option to license certain IP from MD Anderson and exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 19 applications have been nationalized, 2 are pending at the PCT stage, and 2 are pending at the provisional stage. While we have obtained 14 issued U.S. patents and 2 currently allowed to date, we cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and/or their use. However, such claims would not prevent a third party from commercializing alternative compositions that do not include both of the bacterial populations claimed in pending applications, potential applications or patents that have or may issue. There can be no assurance that any such alternative composition will not be equally effective. Further, given that our SER-109 product candidate is a complex composition with some variation from lot-to-lot and that, likewise, third-party compositions may have similar complexity and variability, it is possible that a patent claim may provide coverage for some but not all lots of a product candidate or third-party product. These and other factors may provide opportunities for our competitors to design around our patents, should they issue.

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

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

We may be subject to third-party preissuance submissions of prior art to the United States Patent and Trademark Office, or USPTO, or in a foreign jurisdiction in which our applications are filed, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, on April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo. See “—*Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.*” The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo has appealed certain aspects of the Opposition Division’s decision, as have we and other opponents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

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

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

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

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

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

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

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

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

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

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

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

The full impact of these decisions is not yet known. For example, in view of these and subsequent court decisions, the USPTO has issued various materials to patent examiners providing guidance for determining the patent eligibility of claims reciting laws of nature, natural phenomena or natural products. Our current product candidates include natural products, therefore, this decision and its interpretation by the courts and the USPTO may impact prosecution, defense and enforcement of our patent portfolio. On March 4, 2014, the USPTO issued a memorandum reflecting the USPTO's interpretation of the cases related to patent eligibility of natural products. The March 4, 2014 memorandum was superseded by interim guidance published on December 15, 2014. Additional guidance was published in July 2015 (July 2015 Update: Subject Matter Eligibility) and May 2016 (May 2016 Subject Matter Eligibility Update). The USPTO's interpretation of the case law and new guidelines for examination may influence, possibly adversely, prosecution and defense of certain types of claims in our portfolio.

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

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

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

We are aware of numerous patents and pending applications owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. We are aware of several pending patent applications containing one or more claims that could be construed to cover some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of third-party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use. On April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo has appealed certain aspects of the Oppositions Division's decision, as have we and other opponents.

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

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

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

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Operations

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

In 2020, a strain of novel coronavirus disease, COVID-19, was declared a pandemic and spread across the world, including throughout the United States, Europe, and Asia. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices, restricted on-site staff to only those required on-site to execute their job responsibilities and limited the number of staff in any given research and development laboratory. On March 30, 2020, as a result of the COVID-19 pandemic, we halted further enrollment of the recently completed ECOSPOR III trial, and we are now actively enrolling patients in our SER-109 open-label study to expand the safety database to meet the FDA's recommendation that our safety database for SER-109 include at least 300 patients. Additionally, SER-287 development activity was impacted by the COVID-19 pandemic and by multiple clinical sites halting non-essential procedures, including endoscopies, and while enrollment is now complete, site staff must still remain available to finalize study participant data. We are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity, including on the SER-401 Phase 1b study in metastatic melanoma and the SER-301 Phase 1b study in ulcerative colitis. Mitigation activities to minimize COVID-19-related operation disruptions are ongoing, however, given the severity and evolving nature of the situation, the timing of clinical readouts is uncertain. As a result of the COVID-19 outbreak, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

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

- refusal of the FDA or other regulatory authorities to accept data from clinical trials in affected geographies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

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

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

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

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

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

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

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

We currently have limited international operations, but our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. We currently conduct clinical studies in Canada, Australia and New Zealand. We may 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. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;

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

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

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

Despite the implementation of a formal, comprehensive cyber-security program, our internal computer systems and data and those of our current and future contractors and consultants are vulnerable to damage or compromise from computer viruses, unauthorized access, ransomware, human error, loss of data privacy, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. While we are not aware of any such material system failure, accident or security breach to date, there have been successful but immaterial cyber-attacks, and if such an event were to occur again in a more material manner and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed.

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

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

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- additional exposure to cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;

- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

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

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

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

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials such as human stool. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury, including from the novel coronavirus SARS-CoV-2, which causes the COVID-19 disease, from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

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

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

As of December 31, 2020, we had net operating loss carryforwards, or NOLs, of \$390 million for federal income tax purposes and \$386.9 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal and state NOLs begin to expire in various amounts in 2035, provided that federal NOLs generated in taxable years after December 31, 2017 will not be subject to expiration. As of December 31, 2020, we also had federal and state research and development and other tax credit carryforwards of approximately \$36.4 million and \$7.5 million, respectively, available to reduce future income tax liabilities. Our federal and state tax credit carryforwards begin to expire in various amounts in 2031 and 2028, respectively. The federal research and development tax credit carryforwards include an orphan drug credit carryforward of \$20.7 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, a corporation that undergoes an “ownership change” is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income and income taxes. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5% of a corporation’s

stock exceeds 50 percentage points over a three-year period. We believe we may have experienced an ownership change in the past and may experience ownership changes in the future because of future transactions in our stock, some of which may be outside our control. If we undergo future ownership changes, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets. NOLs arising in periods beginning after December 31, 2017 may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020, which change may require us to pay federal income taxes in future years despite federal NOLs in prior years.

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

In October 2019, we entered into a loan and security agreement with Hercules pursuant to which a term loan facility in aggregate principal amount up to \$50.0 million, or the Term Loan Facility, is 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. We did not meet the milestone requirements for the second tranche under the Term Loan Facility, and as such, the additional second tranche amount of up to \$12.5 million is not available for us to borrow. The third tranche, which allows us to borrow an additional \$12.5 million, will be available upon Hercules' approval on or prior to June 30, 2021. The Term Loan Facility is secured by a lien on substantially all of our assets, other than intellectual property. We also agreed not to pledge or secure our intellectual property to others.

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

Risks Related to Our Common Stock

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

Our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 68% of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

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

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 no longer an “emerging growth company” and, as a result, are subject to certain enhanced disclosure requirements.

The last day of the fiscal year following the fifth anniversary of our IPO was December 31, 2020. As a result, commencing January 1, 2021, we are subject to certain requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. Compliance with these enhanced disclosure requirements will increase our costs and could negatively affect our results of operations and financial condition. Moreover, if we become an accelerated filer or large accelerated filer in the future, we would be required to comply with the auditor attestation requirements under Section 404 of the Sarbanes Oxley Act of 2002, as amended, or Section 404.

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 more than \$700 million 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 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, our loan and security agreement with Hercules Capital currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

General Risk Factors

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

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

- the success of competitive products or technologies;
- actual or anticipated changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- developments related to any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and may make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;

- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses, particularly now that we are no longer an emerging growth company or after we are no longer a smaller reporting company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Research and Offices

Our corporate headquarters is located in Cambridge, Massachusetts, where we lease approximately 83,396 square feet of office, laboratory, and pilot manufacturing space under a lease that expires in November 2023.

Clinical Manufacturing

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

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

Item 3. Legal Proceedings

Opposition Proceeding

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

Item 4. Mine Safety Disclosures

Not applicable.

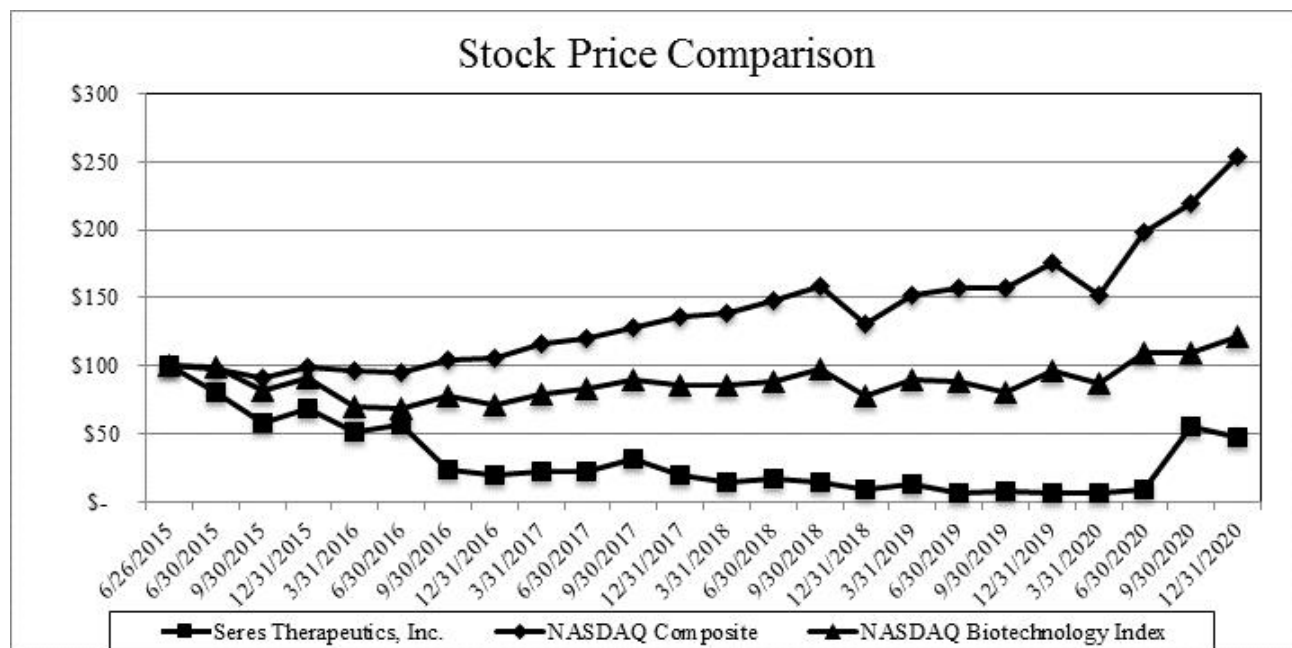
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

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

Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock between June 26, 2015 (the date of our initial public offering) and December 31, 2020, with the cumulative total return of (a) the Nasdaq Biotechnology Index and (b) the Nasdaq Composite Index, over the same period. This graph assumes the investment of \$100 on June 26, 2015 in our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index and assumes the reinvestment of dividends, if any. The graph assumes our closing sales price on June 26, 2015 of \$51.40 per share as the initial value of our common stock and not the initial offering price to the public of \$18.00 per share.



Holders

As of February 24, 2021, there were approximately 11 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

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

Recent Sales of Unregistered Securities

We did not make any sales of unregistered securities during the quarter ended December 31, 2020.

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, 2020.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Important factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Summary Risk Factors" and Part I and Item 1A. "Risk Factors" of this Annual Report on Form 10-K.

Overview

We are a microbiome therapeutics company developing a novel class of live biotherapeutic drugs, which are consortia of microbes designed to treat disease by modulating the microbiome to treat or prevent disease by repairing the function of a disease susceptible microbiome to a non-disease state. We have an advanced drug pipeline with late-stage clinical assets and a differentiated microbiome therapeutics drug discovery and development platform including GMP manufacturing capabilities for this novel drug modality.

Our highest-priority is preparing the SER-109 BLA for submission to the FDA; we are focused on completing acquisition of the required safety database necessary for approval to treat CDI, with SER-109. Additionally, using our microbiome therapeutics platform, we are focusing our resources on obtaining clinical results from our clinical programs in ulcerative colitis, or UC, a form of IBD, with SER-287 and SER-301, with SER-401 in patients with metastatic melanoma and with SER-155 to prevent mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allo-HSCT or solid organ transplants.

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

All our product candidates other than SER-109, SER-287, SER-301, SER-155 and SER-401 are still in preclinical development or early stage discovery. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Since our inception, we have incurred significant operating losses. Our net loss was \$89.1 million for the twelve months ended December 31, 2020. As of December 31, 2020, we had an accumulated deficit of \$548.8 million and cash, cash equivalents and short- and long-term investments totaling \$303.4 million. Based on our current plans and forecasted expenses, we believe that our existing cash, cash equivalents and investments as of December 31, 2020, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements for at least the next 12-months from issuance of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

In August 2020, we completed an underwritten public offering in which we sold 10,500,000 shares of our common stock at a public offering price of \$21.50 per share. In addition, we granted the underwriters a 30-day option to purchase up to an additional 1,575,000 shares of our common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. We received aggregate net proceeds from the offering of approximately \$243.7 million after deducting underwriting discounts and commissions and offering expenses payable by us.

Also, in August 2020, we entered into a Securities Purchase Agreement with Société des Produits Nestlé S.A., or Nestlé, for the sale of 959,002 shares of our common stock at a purchase price of \$20.855 per share, or the "concurrent placement." We received aggregate net proceeds from the concurrent placement of approximately \$19.9 million after deducting offering expenses payable by us. See "—Liquidity and Capital Resources."

Impact of Novel Coronavirus

We are monitoring the global outbreak and spread of the novel strain of coronavirus, or COVID-19, and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a work from home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees, and other business partners in light of COVID-19. The impact of COVID-19 on our future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the

United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, the effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. See “Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition” in Part I, Item 1A of this Annual Report on Form 10-K.

SER-109

SER-109 is an oral, purified bacterial spore-based microbiome therapeutic candidate consisting of a consortium of purified bacteria. Our SER-109 manufacturing process includes inactivation and clearance steps designed to eliminate potential pathogens. SER-109 is designed to prevent further recurrences of CDI in patients with a history of multiple infections by modulating the microbiome to a state that resists *C. difficile* colonization and growth. SER-109, if approved, is intended to treat individuals with recurrent CDI, a patient population which includes approximately 170,000 individuals per year in the United States. We completed enrollment with 182 patients with multiply recurrent CDI in ECOSPOR III. All patients who entered ECOSPOR III must have tested positive for *C. difficile* toxin, as currently recommended by the Infectious Diseases Society of America guidelines (McDonald Clin Infect Dis 2018). 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 of comparing the *C. difficile* recurrence rate in subjects who receive SER-109 versus placebo at up to eight weeks after dosing.

In August 2020, we reported positive topline results from the interim analysis of the pivotal Phase 3 ECOSPOR III study evaluating SER-109 for recurrent CDI. Those results showed that SER-109 administration resulted in a highly statistically significant absolute decrease of 30.2% in the proportion of patients who experienced a recurrence in CDI within eight weeks of administration versus placebo, the study’s primary endpoint, and which remained consistent at 12-weeks end point with a 31.1% absolute decrease. At eight weeks of treatment, 11.1% of patients administered SER-109 experienced a CDI recurrence, versus 41.3% of placebo patients. The study results were equally compelling when characterized by the alternative metric of sustained clinical response, where 89% of patients in the SER-109 arm achieved this objective at eight weeks. Subsequent analyses from the completed Phase 3 study using the final statistically defined Intent-to-Treat population show that 12.4% of subjects experienced a recurrence, versus 39.8% on placebo, which represents a relative risk of 0.32 (95% CI 0.18-0.58; $p < .001$), with an absolute risk reduction of 27.4% and a relative risk reduction of 69%. The percent on SER-109 with a sustained clinical response was approximately 88%. The number-needed-to treat was 3.7. In the same updated analysis, the 12 week rate of recurrence in the SER-109 arm was 18.0%, compared to a rate of 46.2% in the placebo arm, representing an absolute risk reduction of 28% (relative risk 0.40; 95% CI 0.24-0.65; p -value = 0.002), and thereby consistent with the results seen at eight weeks. Results across stratifications of age and antibiotics remained similar. The study’s efficacy results related to the primary endpoint from all analyses exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a biological license application, or BLA. The efficacy remained durable through twenty-four weeks of follow-up.

The SER-109 safety results observed to-date were favorable, with an adverse event profile comparable to placebo. We are actively enrolling patients in our SER-109 open-label study, which also admits patients with a single recurrence of CDI, to expand the safety database to meet the FDA threshold of at least 300 patients.

SER-287

SER-287, an oral, consortium of purified bacteria, is a microbiome therapeutic candidate designed to normalize the gastrointestinal microbiome of individuals with UC. In December 2018, we commenced a three-arm placebo-controlled Phase 2b clinical trial that was designed to evaluate SER-287 in approximately 201 patients with mild-to-moderate UC. Two groups of patients are receiving different doses of SER-287, both following pre-conditioning with a short course of oral vancomycin. A third study arm will receive placebo. The study’s primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Patients then enter a 2-week exploratory maintenance follow-up period. Endoscopic improvement will be measured as a secondary efficacy measure. Based on feedback from the FDA, if the data from this trial is positive, we expect that the Phase 2b clinical trial could be one of two pivotal trials to enable a BLA to be submitted for SER-287 for the treatment of UC. SER-287 development activity has been adversely impacted by the COVID-19 pandemic.

There are approximately 700,000 UC patients in the United States and fewer than one-third of patients on current therapies achieve remission. Approved treatments are often inadequate to control disease activity and are often associated with significant side effects, including immunosuppression. We believe that SER-287 may address underlying drivers of inflammation in UC and, based on the favorable tolerability profile observed in our clinical trials of SER-287, has the potential to be developed as both a foundational monotherapy, as well as a combination therapy with other UC drugs. SER-287 has been granted Fast Track Designation by the FDA for the induction and maintenance of clinical remission in adult subjects with active mild-to-moderate UC. SER-287 has been designated an Orphan Drug for pediatric UC by the FDA. We anticipate top-line results in mid-2021.

SER-301

We are also advancing our next generation, rationally-designed, fermented microbiome drug discovery and development capabilities, focusing on advancing SER-301, a therapeutic candidate for UC. We have nominated the SER-301 lead candidate. SER-301 is a consortia of bacteria designed using our 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. SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF- α driven inflammation in IECs, and modulate UC-relevant anti-inflammatory, innate and adaptive immune pathways. SER-301 is being produced by our advanced fermentation, formulation and delivery platforms. It includes strains delivered in spore form, as well as strains fermented in non-spore (vegetative) form and delivered using enterically-protected technology designed to release in the colon.

We have initiated clinical development activities for SER-301, and in November 2020 we enrolled our first patient in the SER-301 Phase 1b study. This initial clinical study of SER-301 is being conducted in Australia and New Zealand. As a result of enrolling the first patient in the clinical study, we received a \$10.0 million milestone payment under our collaboration and license agreement, or the License Agreement, with Société des Produits Nestlé S.A., or Nestlé, successor in interest to Nestec, Ltd.

SER-155

We have nominated the SER-155 lead candidate, consortium of cultivated bacteria microbiome drug and are advancing the candidate into clinical development. The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan Kettering Cancer Center showing that allo-HSCT patients with decreased diversity of commensal microbes are significantly more likely to die due to infection and/or lethal graft versus host disease, or GvHD. SER-155 is consortia of cultivated bacteria designed using our reverse translational discovery platform to prevent mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation (allo-HSCT) or solid organ transplants. SER-155 lead candidate is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. In November 2017, we were awarded a highly competitive grant from CARB-X to support continued preclinical research and early development work for SER-155. In 2019, Seres was awarded additional funding from CARB-X to support clinical development of SER-155, including support through IND filing and Phase 1b evaluation. The 2019 CARB-X grant provides us with an additional \$4.8 million of funding for research, manufacture, and IND submission, with potential for an additional \$7.0 million for Phase 1b development, upon completion of milestones. We expect to initiate clinical development of SER-155 in the first half of 2021.

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

- complete the clinical development and prepare for commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-301 for the treatment of UC;
- initiate clinical development of SER-155 for the prevention of mortality due to GvHD in immunocompromised patients, including in patients receiving allo-HSCT;
- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- make strategic investments in manufacturing capabilities;
- make strategic investments in our research discovery and development platforms and 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.

SER-401

SER-401, an oral consortium of purified bacteria is a microbiome therapeutic candidate comprising a bacterial signature similar to that observed in checkpoint inhibitor immunotherapy responders. In March 2019, the first patient was dosed in the Phase 1b clinical study with MD Anderson and PICI, to evaluate SER-401's potential to augment the response of anti-PD-1 checkpoint inhibitor therapy. The study is designed to enroll 30 patients with metastatic melanoma who are being treated with nivolumab, an anti-PD-1 therapy. Patients are randomized at a 2-to-1 ratio to either SER-401 or placebo. The study's primary endpoints are to evaluate safety and tolerability. Its secondary endpoints are to evaluate the correlation of microbiome biomarkers of response to various clinical and immunological outcome measures.

Seres continues to monitor the impact of the COVID-19 pandemic on company operations and ongoing clinical development activity, including on the SER-401 Phase 1b study in metastatic melanoma. Mitigation activities to minimize COVID-19-related operation disruptions are ongoing, however, given the severity and evolving nature of the situation, the timing of the SER-401 Phase 1b clinical readout is uncertain.

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. See "Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition" in Part I, Item 1A of this Annual Report on Form 10-K. 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.

Intellectual Property

Patent Portfolio

We have an extensive patent portfolio directed to rationally designed ecologies of spores and microbes. The portfolio includes both company-owned patents and applications, and those that we have rights to as licensee. For example, our portfolio includes an option to license foundational intellectual property related to the use of bacteria in combination with checkpoint inhibitors from MD Anderson. The patents and applications included in our portfolio cover both composition of matter and methods (*e.g.*, method of treating). Our intellectual property rights related to SER-109 (*C. difficile*) and SER-287 (ulcerative colitis) extend through 2033. We plan on continuing to broaden our patent portfolio. Currently, we have 23 active patent application families, which includes 19 nationalized applications, 2 pending at the PCT stage, and 2 pending U.S. provisional applications. To date, we have obtained 14 issued U.S. patents and 2 U.S. patent applications have additionally been allowed.

Regulatory Exclusivity

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

Financial Operations Overview

Revenue

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

Operating Expenses

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

Research and Development Expenses

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

- expenses incurred under agreements with third-parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations that manufacture drug products for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel in our research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the cost of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses. All costs associated with the License Agreement with Nestlé, and the Research Agreement with MedImmune are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

Our primary focus of research and development since inception has been on our 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 pre-clinical 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 and, as such, are classified as costs of our microbiome therapeutics platform research, along with external costs directly related to our microbiome therapeutics platform.

The table below summarizes our research and development expenses incurred on our platform and by product development program for those that have begun clinical development.

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Microbiome therapeutics platform	\$ 53,961	\$ 50,307	\$ 59,125
SER-109	14,939	10,281	18,482
SER-287	16,347	17,398	11,579
Early stage programs	5,323	2,155	6,769
Total research and development expenses	<u>\$ 90,570</u>	<u>\$ 80,141</u>	<u>\$ 95,955</u>

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we complete our open-label clinical study of SER-109, advance the clinical development of SER-287, continue to discover and develop additional product candidates, including SER-301, SER-155 and SER-401 and pursue later stages of clinical development of our product candidates.

General and Administrative Expenses

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

Our general and administrative expenses may increase in the future if we increase our headcount to support the potential growth in our research and development activities and the potential commercialization of our product candidates. We also may continue to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the requirements of the Securities and Exchange Commission, director and officer insurance costs and investor and public relations costs.

Restructuring

In February 2019, we implemented corporate changes to focus our resources on advancing our clinical-stage therapeutic candidates. As a result, we are concentrating on completing our SER-287 Phase 2b study in mild-to-moderate UC patients, expanding the SER-109 safety database to meet the FDA threshold of at least 300 patients, advancing the SER-401 Phase 1b study in collaboration with the PICI and MD Anderson to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma, and advancing SER-301 into clinical development. In connection with the prioritization of these therapeutic candidates, we made changes to our management team and reduced headcount by approximately 30 percent.

Other (Expense) Income, Net

Interest (Expense) Income, Net

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

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

Other Income

Other income primarily consists of sublease income.

Income Taxes

Since our inception in 2010, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2020, we had federal and state net operating loss carryforwards of \$390.0 million and \$386.9 million, respectively, both of which begin to expire in 2035. As of December 31, 2020, we also had federal and state research and development tax credit carryforwards of \$36.4 million and \$7.5 million, respectively, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of \$20.7 million.

Critical Accounting Policies and Significant Judgments and Estimates

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

Revenue Recognition

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

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligation(s) in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligation(s) in the contract; and
- (v) recognize revenue when (or as) the entity satisfies a performance obligation.

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

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

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

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

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

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

Collaboration Revenue

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

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

Licenses of Intellectual Property

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

Milestone Payments

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

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

Royalties

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

Manufacturing Supply Services

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

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

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. 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, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Change
	2020	2019	
	(in thousands)		
Revenue:			
Collaboration revenue - related party	\$ 11,897	\$ 27,188	\$ (15,291)
Grant revenue	4,157	1,102	3,055
Collaboration revenue	17,161	6,215	10,946
Total revenue	33,215	34,505	(1,290)
Operating expenses:			
Research and development	90,570	80,141	10,429
General and administrative	30,775	24,748	6,027
Restructuring expenses	—	1,492	(1,492)
Total operating expenses	121,345	106,381	14,964
Loss from operations	(88,130)	(71,876)	(16,254)
Other (expense) income:			
Interest income	946	1,033	(87)
Interest expense	(2,924)	(502)	(2,422)
Other income	981	1,066	(85)
Total other (expense) income, net	(997)	1,597	(2,594)
Net loss	\$ (89,127)	\$ (70,279)	\$ (18,848)

Revenue

Total revenue was \$33.2 million and \$34.5 million for the years ended December 31, 2020 and 2019, respectively. The revenue for the year ended December 31, 2020 related primarily to \$17.2 million associated with our Research Agreement with MedImmune, a wholly owned subsidiary of AstraZeneca Inc. The increase of \$10.9 million in revenue from our Research Agreement from fiscal 2019 to fiscal 2020 is primarily related to AstraZeneca's election to terminate the Research Agreement by and in accordance with its terms. As a result of this election and because we no longer had any performance obligations as of December 31, 2020, we recognized all deferred revenue in fiscal 2020. Additionally, we recognized \$11.9 million of revenue associated with our license and collaborative agreement with Nestec Ltd., or the License Agreement. This was a \$15.3 million decrease from fiscal 2019, which was primarily a result of an increase in our total estimated costs expected to complete our single performance obligation driven by our active enrollment of patients in our open-label study for SER-109 in order to expand the safety database to meet the FDA threshold of at least 300 patients and SER-287 clinical development activity being adversely impacted by the COVID-19 pandemic. The decrease was partially off-set by cumulative catch-up revenue associated with the increase of \$10.0 million to the transaction price related to the milestone payment we received from Nestlé for initiating the SER-301 Phase 1b study. Lastly, we recognized \$4.2 million of grant revenue in fiscal 2020, which was a \$3.1 million increase from fiscal 2019. This is primarily the result of the advancement of our SER-155 research and development activities, which are reimbursable under the terms of the CARB-X grant.

Research and Development Expenses

	Year Ended December 31,		Change
	2020	2019	
	(in thousands)		
Microbiome therapeutics platform	\$ 53,961	\$ 50,307	\$ 3,654
SER-109	14,939	10,281	4,658
SER-287	16,347	17,398	(1,051)
Early stage programs	5,323	2,155	3,168
Total research and development expenses	<u>\$ 90,570</u>	<u>\$ 80,141</u>	<u>\$ 10,429</u>

Research and development expenses were \$90.6 million for the year ended December 31, 2020, compared to \$80.1 million for the year ended December 31, 2019. The increase of \$10.4 million was due primarily to the following:

- an increase of \$3.7 million in research expenses related to our microbiome therapeutics platform due primarily to an increase of \$5.0 million in employee and consultant expenses. This was partially offset by a decrease of \$1.8 million in facility and supply costs.
- an increase of \$4.7 million in expenses related to our SER-109 program, due primarily to an increase of \$1.7 million in contract manufacturing, an increase of \$1.3 million in employee and consultant expenses, an increase of \$1.0 million in sequencing costs, an increase of \$1.0 million in facilities and supply costs, and partially offset by a decrease of \$0.4 million in clinical trial consulting expenses;
- a decrease of \$1.1 million in expenses of our SER-287 program primarily driven by a decrease in contract manufacturing of \$3.4 million, and partially offset by an increase of \$1.2 million in facility and supplies, an increase of \$0.7 million in clinical trial consulting expenses, and an increase of \$0.3 million employee and consultant expenses;
- an increase of \$3.2 million in expenses of our early stage programs primarily driven by an increase in clinical trials costs.

We expect that our research and development expenses may increase in the foreseeable future as we advance the clinical development of SER-109, SER-287 and SER-301, and continue to discover and develop additional product candidates, including SER-155 and SER-401, and pursue later stages of clinical development of our product candidates.

General and Administrative Expenses

	Year Ended December 31,		Change
	2020	2019	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 11,078	\$ 9,586	\$ 1,492
Professional fees	13,781	9,279	4,502
Facility-related and other	5,916	5,883	33
Total general and administrative expenses	<u>\$ 30,775</u>	<u>\$ 24,748</u>	<u>\$ 6,027</u>

General and administrative expenses were \$30.8 million for the year ended December 31, 2020, compared to \$24.7 million for the year ended December 31, 2019. The increase of \$6.0 million was primarily due to the following:

- an increase in personnel related costs of \$1.5 million primarily due to the increase of \$0.8 million in salary cost, payroll tax expense, and benefit costs, and a \$0.4 million increase in stock-based compensation expense; and
- an increase in professional fees of \$4.5 million primarily due to a \$4.1 million increase in SER-109 commercial readiness and a \$0.6 million increase in recruiting fees.

Restructuring

During the year ended December 31, 2019 we recorded charges of \$1.5 million related to severance and other termination benefits, of which \$1.3 million was paid during the year ended December 31, 2019. The remaining \$0.2 million of restructuring charges were paid in fiscal 2020. No restructuring charges were recorded during the years ended December 31, 2018 and December 31, 2020.

Other (Expense) Income, Net

Other (expense) income, net for the year ended December 31, 2020 was \$1.0 million of expense, compared to \$1.6 million of income for the year ended December 31, 2019. The \$2.6 million decrease in other (expense) income, net was primarily due to \$2.9 million of interest expense associated with our term loan with Hercules, associated with the term loan being outstanding for the entirety of fiscal 2020 compared to partially outstanding in fiscal 2019.

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Change
	2019	2018	
	(in thousands)		
Revenue			
Collaboration revenue - related party	\$ 27,188	\$ 26,917	\$ 271
Grant revenue	1,102	1,350	(248)
Collaboration revenue	6,215	—	6,215
Total revenue	34,505	28,267	6,238
Operating expenses:			
Research and development	80,141	95,955	(15,814)
General and administrative	24,748	32,596	(7,848)
Restructuring expenses	1,492	—	1,492
Total operating expenses	106,381	128,551	(22,170)
Loss from operations	(71,876)	(100,284)	28,408
Other income:			
Interest income	1,033	1,172	(139)
Interest expense	(502)	—	(502)
Other income	1,066	170	896
Total other income, net	1,597	1,342	255
Net loss	\$ (70,279)	\$ (98,942)	\$ 28,663

Revenue

Total revenue was \$34.5 million and \$28.3 million for the years ended December 31, 2019 and 2018, respectively. The revenue for both periods principally relates to the recognition of amounts received under the License Agreement. The increase is mainly due to recognition of amounts received under the Research Agreement entered into in March 2019.

Research and Development Expenses

	Year Ended December 31,		Change
	2019	2018	
	(in thousands)		
Microbiome therapeutics platform	\$ 50,307	\$ 59,125	\$ (8,818)
SER-109	10,281	18,482	\$ (8,201)
SER-287	17,398	11,579	\$ 5,819
Early stage programs	2,155	6,769	(4,614)
Total research and development expenses	<u>\$ 80,141</u>	<u>\$ 95,955</u>	<u>\$ (15,814)</u>

Research and development expenses were \$80.1 million for the year ended December 31, 2019, compared to \$96.0 million for the year ended December 31, 2018. The decrease of \$15.8 million was due primarily to the following:

- a decrease of \$8.8 million in research expenses related to our microbiome therapeutics platform, due primarily to a decrease of \$9.3 million in employee and consultant expenses, and partially offset by an increase of \$0.4 million of professional fees and an increase of \$0.2 million of facility and supply costs;
- a decrease of \$8.2 million in expenses related to our SER-109 program, due primarily to a decrease of \$3.2 million in contract manufacturing costs, a \$3.1 million decrease in clinical trial consulting expenses, a \$1.0 million decrease in facility and supply costs, and a decrease of \$0.9 million in sequencing costs;
- an increase of \$5.8 million in expenses of our SER-287 program primarily driven by an increase in clinical trials costs of \$4.8 million, an increase in contract manufacturing of \$3.4 million, this is partially offset by a \$1.2 million decrease in facility and supply costs, and a \$0.8 million decrease sequencing and a \$0.4 million decrease in employee and consultant expenses, and;
- a decrease of \$4.6 million in expenses of our early stage programs primarily driven by a decrease in clinical trial costs of \$2.8 million and decrease in sequencing costs \$1.0 million.

General and Administrative Expenses

	Year Ended December 31,		Change
	2019	2018	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 9,586	\$ 15,765	\$ (6,179)
Professional fees	9,279	7,609	1,670
Facility-related and other	5,883	9,222	(3,339)
Total general and administrative expenses	<u>\$ 24,748</u>	<u>\$ 32,596</u>	<u>\$ (7,848)</u>

General and administrative expenses were \$24.7 million for the year ended December 31, 2019, compared to \$32.6 million for the year ended December 31, 2018. The decrease of \$7.8 million was primarily due to the following:

- a decrease in personnel related costs of \$6.2 million primarily due to the decrease in stock-based compensation expense of \$4.6 million and a decrease in salary costs of \$1.8 million;
- an increase in professional fees of \$1.7 million primarily due to an increase in consulting fees of \$0.7 million, an increase in accounting related fees of \$0.7 million, and an increase in legal fees of \$0.3 million; and
- a decrease in facility-related and other costs of \$3.3 million primarily due to a decrease in information technology expenses.

Restructuring

During the year ended December 31, 2019 we recorded charges of \$1.5 million related to severance and other termination benefits, of which \$1.3 million was paid during the year ended December 31, 2019. No restructuring charges were recorded during the year ended December 31, 2018.

Other Income, Net

Other income, net for the year ended December 31, 2019 was \$1.6 million, compared to \$1.3 million for the year ended December 31, 2018. The \$0.3 million increase in other income, net was primarily due to sublease income of \$0.9 million. This increase was partially offset by interest expense of \$0.5 million incurred under the Term Loan Facility.

Liquidity and Capital Resources

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

In August 2020, we completed an underwritten public offering in which we sold 10,500,000 shares of our common stock at a public offering price of \$21.50 per share. In addition, we granted the underwriters a 30-day option to purchase up to an additional 1,575,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. We received aggregate net proceeds from the offering of approximately \$243.7 million after deducting underwriting discounts and commissions and offering expenses payable by us.

In August 2020, we entered into a Securities Purchase Agreement with Nestlé for the sale of 959,002 shares of our common stock at a purchase price of \$20.855 per share (the “concurrent placement”). We received aggregate net proceeds from the concurrent placement of approximately \$19.9 million after deducting offering expenses payable by us.

In November 2019, we entered into a common stock sales agreement, or the 2019 Sales Agreement, with Cowen to sell shares of our common stock with aggregate gross sales proceeds of up to \$25.0 million, from time to time, through an ATM under which Cowen acts as sales agent. In March 2020, in connection with filing an updated registration statement on Form S-3 (File No. 333-237033), we entered into a new common stock sales agreement, or the 2020 Sales Agreement, with Cowen on substantially the same terms as the 2019 Sales Agreement and terminated the 2019 Sales Agreement. During the year ended December 31, 2020, we sold approximately 5.8 million shares of common stock under the 2019 Sales Agreement and the 2020 Sales Agreement, as applicable, at an average price of approximately \$4.40 per share, raising aggregate net proceeds of approximately \$24.8 million after deducting an aggregate commission of approximately 3%.

As of December 31, 2020, we had cash, cash equivalents and short- and long-term investments totaling \$303.4 million and an accumulated deficit of \$548.8 million. Based on our current plans and forecasted expenses, we believe that our cash, cash equivalents and investments as of December 31, 2020, will enable us to fund our operating expenses, debt service obligations and capital expenditures for at least the next 12-months from issuance of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Collaboration Agreements

Agreement with Nestlé

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

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

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

Agreement with AstraZeneca

In March 2019, we entered into the Research Agreement with MedImmune, a wholly owned subsidiary of AstraZeneca. Pursuant to the Research Agreement, we and AstraZeneca agreed to conduct certain pre-clinical and development activities and may conduct certain clinical research with the goal of advancing the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy, including potential synergy with AstraZeneca compounds in accordance with a mutually agreed research plan. Pursuant to the Research Agreement, we agreed not to conduct research or development of any microbiome products specifically designed by us during the term of the Research Agreement for the treatment of cancer with or on behalf of any third party without the prior approval of the joint steering committee for the Research Agreement until at least three years after the effective date of the Research Agreement.

AstraZeneca has agreed to bear all costs of conducting its activities under the research plan and to reimburse us for certain costs incurred under the research plan. Additionally, AstraZeneca has agreed to pay to us a total of \$20.0 million in three equal installments, the first of which we received in April 2019, the second of which we received in December 2019, and the third of which will become due on January 4, 2021. Such payments are payable even if the Research Agreement is terminated in accordance with its terms, unless the Research Agreement is terminated by AstraZeneca for our uncured material breach.

We also granted AstraZeneca an exclusive option to negotiate exclusive license rights to certain of our technologies and assets. If AstraZeneca exercises this option, we have agreed to enter into good faith negotiations with them for terms and conditions of such license agreement for a specified time period.

In December 2020, we received written notice from AstraZeneca that they elected to terminate the Research Agreement by and in accordance with its terms. The termination of the Research Agreement will be effective on April 2, 2021 (the "Termination Date"), which is 120 days from the date of the notice. We received the third and final \$6.7 million installment of the aggregate \$20.0 million upfront payment due under the Research Agreement in January 2021.

Loan and Security Agreement with Hercules

In October 2019, we entered into a loan and security agreement with Hercules, pursuant to which a term loan in an aggregate principal amount of up to \$50.0 million, or the Term Loan 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. We did not meet the milestone requirements for the second tranche under the Term Loan Facility, and as such, the additional second tranche amount of up to \$12.5 million is not available for us to borrow. The third tranche, which allows us to borrow an additional \$12.5 million, will be available upon Hercules' approval on or prior to June 30, 2021.

Advances under the Term Loan Facility will bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.40%, and (ii) 9.65%. We will make interest only payments through December 1, 2021, or extended to June 1, 2022 upon satisfaction of certain milestones, and will then repay the principal balance and interest of the advances in equal monthly installments after the interest only period and continuing through November 1, 2023. We paid Hercules a commitment fee of \$0.4 million at the closing. We may prepay advances under the loan and security agreement with Hercules, in whole or in part, at any time subject to a prepayment charge equal to: (a) 3.0 % of amounts so prepaid, if such prepayment occurs during the first year; (b) 2.0% of the amount so prepaid, if such prepayment occurs during the second year, and (c) 1.0% of the amount so prepaid, if such prepayment occurs after the second year. Upon prepayment or repayment of all or any of the term loans, we will pay (in addition to the prepayment premium) an end of term charge of 4.85% of the aggregate funded amount under the Term Loan Facility.

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

The Term Loan Facility includes affirmative and negative covenants applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on our transferring collateral, making changes to the nature of our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, engaging in transactions with affiliates, creating liens and selling assets, in each case subject to certain exceptions, including, among others, the ability for us to issue up to \$150.0 million in convertible notes and entering into exclusive outbound licenses for our intellectual property. The Term Loan Facility also includes a liquidity covenant that commences either October 31, 2020, or December 31, 2020 based upon our satisfying certain performance milestones. If our market capitalization exceeds \$350.0 million, we do not have to comply with the liquidity covenant if such covenant is required.

The Term Loan Facility also includes events of default, the occurrence and continuance of which provide Hercules with the right to demand immediate repayment of all principal and unpaid interest, and to exercise remedies against us and the collateral. These events of default include, among other things and subject to customary exceptions: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the loan and security agreement with Hercules or other loan documents on a timely basis; (iii) failure to observe certain covenants under the loan and security agreement with Hercules; (v) occurrence of a material adverse effect; (vi) material misrepresentation by us; (vii) occurrence of any default under any other agreement involving material indebtedness; and (viii) certain material money judgments.

On April 16, 2020, we entered into an amendment to the loan and security agreement with Hercules, 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, pursuant to which we received loan proceeds of \$2.9 million (the "Loan"), 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.

As of December 31, 2020 and December 31, 2019, the outstanding principal under the Term Loan Facility was \$25.0 million and \$24.6 million, respectively. For a further description of the Term Loan Facility, see Note 9 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Cash Flows

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

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Cash used in operating activities	\$ (93,610)	\$ (76,520)	\$ (62,854)
Cash (used in) provided by investing activities	\$ (158,891)	\$ (30,518)	\$ 112,318
Cash provided by financing activities	\$ 303,424	\$ 86,231	\$ 268
Net increase (decrease) in cash and cash equivalents and restricted cash	\$ 50,923	\$ (20,807)	\$ 49,732

Operating Activities

During the year ended December 31, 2020, operating activities used \$93.6 million of cash, primarily due to a net loss of \$89.1 million and by cash used in changes in our operating assets and liabilities of \$23.2 million and partially offset by non-cash charges of \$18.7 million. Net cash used in changes in our operating assets and liabilities during the year ended December 31, 2020 primarily consisted of a \$11.6 million decrease in deferred revenue, a \$4.5 million decrease in operating lease liabilities, a \$1.2 million decrease in accounts payable, a \$7.6 million increase in accounts receivable, a \$2.2 million increase in prepaid expenses and other current assets, and offset by a \$3.8 million decrease in accrued expenses and other liabilities. The decrease in deferred revenue is due to recognition of revenue during the year and partially offset by \$10.0 million associated with the increase in the transaction price for the License Agreement for the initiation of the Phase 1b study for SER-301. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

During the year ended December 31, 2019, operating activities used \$76.5 million of cash, primarily due to a net loss of \$70.3 million and by cash used in changes in our operating assets and liabilities of \$24.6 million and partially offset by non-cash charges of \$18.4 million. Net cash used in changes in our operating assets and liabilities during the year ended December 31, 2019 consisted of a \$17.5 million decrease in deferred revenue, a \$4.2 million decrease in operating lease liabilities, a \$2.9 million decrease in accrued

expenses and other liabilities, a \$1.8 million increase in accounts receivable and offset in part by a \$3.3 million decrease in prepaid expenses and other current assets. The decrease in deferred revenue is due to recognition of revenue during the year and partially offset by the receipt of \$15.0 million of payments from AstraZeneca under the Research Agreement. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

During the year ended December 31, 2018, operating activities used \$62.9 million of cash, primarily due to a net loss of \$98.9 million and partially offset by cash provided by changes in our operating assets and liabilities of \$11.8 million and non-cash charges of \$24.3 million. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2018 consisted of a \$13.5 million increase in deferred revenue, a \$0.8 million increase in accrued expenses and other liabilities, offset in part by a \$2.1 million decrease in prepaid expenses and other current assets. The increase in deferred revenue is due to the receipt of the \$40 million milestone payments under the License Agreement offset by recognition of collaboration revenue during the year. The increase in accrued expenses was due to the timing of payments.

Investing Activities

During the year ended December 31, 2020, investing activities used \$158.9 million of cash, consisting of purchases of investments of \$218.3 million, and purchases of property and equipment of \$0.6 million; these amounts were partially offset by sales and maturities of investments of \$60.0 million.

During the year ended December 31, 2019, investing activities used \$30.5 million of cash, consisting of purchases of investments of \$46.4 million, and purchases of property and equipment of \$1.0 million; these amounts were partially offset by sales and maturities of investments of \$16.9 million.

During the year ended December 31, 2018, investing activities provided \$112.3 million of cash, consisting of sales and maturities of investments of \$136.1 million; these amounts were partially offset by purchases of investments of \$21.8 million, and purchases of property and equipment of \$1.9 million.

Financing Activities

During the year ended December 31, 2020, net cash provided by financing activities was \$303.4 million. This was a result of \$243.7 million from proceeds from public offering of common stock, net of costs, \$19.9 million of proceeds from the Securities Purchase Agreement, \$24.8 million of proceeds from the at market equity offering, net of commissions, and \$14.4 million from the exercise of stock options.

During the year ended December 31, 2019, net cash provided by financing activities was \$86.2 million in connection with \$60.5 million of proceeds from the public offering of common stock, net of costs, \$25.0 million of proceeds from the issuance of debt, \$0.5 million from the issuance of common stock under at the market sales agreement, \$0.3 million received from the issuance of common stock under our employee stock purchase plan, \$0.2 million from the issuance of restricted common stock, and \$0.1 million from the issuance of common stock and exercise of stock options. These were partially offset by payments for debt issuance costs of \$0.4 million.

During the year ended December 31, 2018, net cash provided by financing activities was \$0.3 million in connection with \$0.3 million received from the issuance of common stock under our employee stock purchase plan and \$0.2 million from the issuance of common stock and exercise of stock options. These were partially offset by payments for employee tax obligations relating to vesting of restricted stock units of \$0.2 million.

Funding Requirements

Our expenses may increase substantially in connection with our ongoing and planned activities related to our pipeline products, which are in clinical development, and our follow-on therapeutic candidates and other programs. In addition, we expect to continue to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- complete the clinical development and prepare for commercialization of SER-109 for patients with recurrent CDI;
- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-301 for the treatment of UC;
- conduct research and initiate clinical development of SER-155 for the prevention of mortality due to GvHD in immunocompromised patients, including in patients receiving all-HSCT;

- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- make strategic investments in manufacturing capabilities;
- make strategic investments in our research discovery and development platforms and 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 programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the impact of the COVID-19 pandemic;
- the progress and results of our clinical studies and pre-clinical development;
- the cost of manufacturing clinical supplies of 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 the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights as common stockholders. Our loan and security agreement with Hercules currently includes, and any additional debt financing and preferred equity financing, if available, may involve agreements that include, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional debt or preferred equity financing may also require the issuance of warrants, which could potentially dilute our shareholders' ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, in addition to our existing collaboration agreements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

As discussed in Note 1 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date the financial statements are issued. We expect our cash, cash equivalents and short- and long-term investments at December 31, 2020 of \$303.4 million will be sufficient to fund our operating expenses, debt service obligations and capital expenditure requirements for at least the next 12-months from issuance of the financial statements.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2020 and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	2 - 3 Years (in thousands)	4 - 5 Years	More Than 5 Years
Operating lease commitments ⁽¹⁾	\$ 18,009	\$ 6,461	\$ 11,548	\$ —	\$ —
Long-term debt obligation, including interest and end of term charge ⁽²⁾	32,296	3,395	28,901	—	—
Total	\$ 50,305	\$ 9,856	\$ 40,449	\$ —	\$ —

- (1) Amounts in the table reflect payments due under our operating lease agreements that expire between May 2021 and November 2023.
- (2) Amounts in the table reflect payments due for our term loan under an arrangement with Hercules for \$25,000. The amounts in the table above reflect interest-only payments through December 1, 2021 with payments on principal beginning thereafter. For purposes of the table above, interest payments were calculated using an annual interest rate of 9.65%, which was the interest rate in effect as of December 31, 2020. Additionally, the table above includes a payment due upon maturity of the loan of \$1,213. See Note 9 of the consolidated financial statements for further discussion of the Hercules term loan.

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.

Off-Balance Sheet Arrangements

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

Recently Issued 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 Risks

Interest Rate Fluctuation Risk

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

As of December 31, 2020, 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, 2020, we had outstanding borrowings under the Term Loan Facility. We accrue interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.40%, and (ii) 9.65%. An immediate 10% change in the Prime Rate would not have a material impact on our debt-related obligations, financial position or results of operations.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and 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 such date, 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) 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, 2020, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report on our internal control over financial reporting of our registered public accounting firm because we are a non-accelerated filer.

Changes in Internal Control over Financial Reporting

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

Item 9B. Other Information

None.

Item 10. Directors, Executive Officers and Corporate Governance

Director Biographical Information

Name	Age	Position
Dennis A. Ausiello, M.D. (3)	75	Director
Grégory Behar (3)	51	Director
Stephen Berenson (3)	60	Chairman of the Board of Directors
Paul R. Biondi (2)	51	Director
Willard H. Dere, M.D. (1)	67	Director
Kurt C. Graves (2)	53	Director
Richard N. Kender (1)(2)	65	Director
Eric D. Shaff	45	President, Chief Executive Officer and Director
Meryl S. Zausner (1)(2)	64	Director

(1) Member of the audit committee.

(2) Member of the compensation and talent committee.

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

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

Grégory Behar has served as a member of our board of directors since December 2014. Mr. Behar has served as Chief Executive Officer of Nestlé Health Science, a business unit of Société des Produits Nestlé S.A., a health sciences company, since July 2014. From July 2011 to July 2014, Mr. Behar was President and Chief Executive Officer of Boehringer Ingelheim Pharmaceuticals Inc. (USA), a pharmaceutical company. From 2010 to July 2011, Mr. Behar was Corporate Vice President Region NECAR (North European Union, Canada and Australasia) for Boehringer-Ingelheim GmbH, a pharmaceutical company. Mr. Behar has served on the board of directors of Axcella Health, Inc. since February 2016 and previously served on the board of directors of Aimmune Therapeutics, Inc. from November 2016 until its acquisition in October 2020. Mr. Behar also serves on the boards of directors of numerous privately held companies. Mr. Behar received his B.S. in Mechanical Engineering from the University of California, Los Angeles, an M.S. in Mechanical Engineering and Manufacturing from EPFL in Switzerland and an M.B.A. from INSEAD in France. We believe that Mr. Behar is qualified to serve on our board of directors because of his extensive business experience in the health sciences and pharmaceutical industries.

Stephen Berenson has served as Chairman of our board of directors since December 2019 and as a member of our board of directors since August 2019. Mr. Berenson has been a Managing Partner at Flagship Pioneering, a life sciences innovation firm, since June 2017. Prior to Flagship, Mr. Berenson spent 33 years in various roles as an investment banker at J.P. Morgan, an investment bank, 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 also serves on the boards of directors of Moderna, Inc. and CiBO Technologies, Inc. Mr. Berenson received an S.B. in Mathematics from the Massachusetts Institute of Technology. We believe that Mr. Berenson is qualified to serve on our board of directors because of his extensive experience working with rapidly-growing companies across various industries.

Paul R. Biondi has served as a member of our board of directors since March 2020. Mr. Biondi is an Executive Partner and President of Pioneering Medicines at Flagship Pioneering, roles he has held since November 2019. Mr. Biondi joined Flagship Pioneering following a seventeen-year tenure at Bristol-Myers Squibb, or BMS, a pharmaceutical company, where he was most recently the

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

Willard H. Dere, M.D. has served as a member our board of directors since July 2017. Dr. Dere has been Professor of Internal Medicine, B. Lue and Hope S. Bettlyon Presidential Endowed Chair in Internal Medicine for Diabetes Research, Executive Director of Personalized Health, and Co-Principal Investigator of the Center for Clinical and Translational Science at the University of Utah Health Sciences Center since November 2014 and Associate Vice President for Research since September 2019. Prior to his professorship, from 2003 until his retirement in October 2014, Dr. Dere held multiple roles at Amgen, Inc., including Head of Global Development, and both corporate and international Chief Medical Officer, and led development of programs in various therapeutic areas. Dr. Dere serves on the boards of directors of several companies, including BioMarin Pharmaceutical, Inc. since 2016, Radius Health since 2014, and Mersana Therapeutics, Inc. since 2018. From October 2016 to December 2017, he served on the board of directors of Ocera Therapeutics. 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.

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

Richard N. Kender has served as a member of our board of directors since October 2014. From October 1978 to September 2013, Mr. Kender held positions in a variety of corporate areas at Merck & Co., Inc., or Merck, a pharmaceutical company, most recently serving as Senior Vice President of Business Development and Corporate Licensing. Mr. Kender has served on the boards of directors of Poxel S.A. since March 2015, Bicycle Therapeutics PLC since July 2019, and ReViral Ltd since November 2019. He previously served on the boards of directors of INC Research Holdings, Inc. between December 2014 and August 2017 and Abide Therapeutics, Inc. between December 2015 and May 2019. Mr. Kender received a B.S. in Accounting from Villanova University and an M.B.A. from Fairleigh Dickinson University. We believe Mr. Kender is qualified to serve on our board of directors because of his finance experience and knowledge of the biotechnology industry.

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

Meryl Zausner has served as a member of our board of directors since August 2018. Ms. Zausner worked for Novartis Pharmaceuticals, Inc., or Novartis, a pharmaceutical company, from 1988 until her retirement in 2017, most recently serving as Chief Financial and Administrative Officer and a member of the Pharmaceutical Executive Committee and Global Finance Leadership Team of Novartis in the United States. At Novartis, she helped launch the Oncology Business Unit, as well as the company's shared services organization. Prior to serving as Chief Financial and Administrative Officer, Ms. Zausner was a member of the Novartis Global Oncology leadership team, where she contributed to the development and commercialization of therapies, including Gleevec® (imatinib). Ms. Zausner has served on the board of directors of the Multiple Myeloma Research Foundation since 2009, and previously served on the board of directors of Neon Therapeutics, Inc. from December 2017 to May 2020. Ms. Zausner received a

B.S. in Accounting and Economics from the University at Albany, SUNY. We believe Ms. Zausner is qualified to serve on our board of directors because of her finance and leadership experience and knowledge of the pharmaceutical industry.

Information about our Executive Officers

Name	Age	Position
Eric D. Shaff	45	President, Chief Executive Officer and Director
Marcus Chapman	50	Vice President, Finance and Principal Financial and Accounting Officer
Thomas J. DesRosier	66	Executive Vice President and Chief Legal Officer
David S. Ege, Ph.D.	46	Executive Vice President and Chief Technology Officer
Matthew Henn, Ph.D.	46	Executive Vice President and Chief Scientific Officer
Lisa von Moltke, M.D.	62	Executive Vice President and Chief Medical Officer
Teresa L. Young, Ph.D.	54	Executive Vice President, Chief Commercial and Strategy Officer

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

Marcus Chapman has served as our Senior Vice President, Finance since January 2018 and as Principal Financial and Accounting Officer since April 2019. Since joining our company in March 2015, he has held positions of increasing seniority, including as our Senior Director of Finance from March 2015 to January 2018. Prior to joining our company, Mr. Chapman served in roles of increasing seniority at Takeda Oncology, or Takeda, the oncology business unit of Takeda Pharmaceuticals Co. Ltd., from August 2007 to March 2015, culminating as Senior Director of Finance and Interim Head of Finance. In these roles, Mr. Chapman oversaw finance functions supporting U.S. sales, U.S. and global marketing, operations, global medical affairs and manufacturing. Prior to Takeda, Mr. Chapman held senior roles at Clarion Healthcare Consulting and Strategic Decisions Group. He began his career at LaSalle Partners in their Investment Banking and Investment Management groups. Mr. Chapman received his B.A. in Economics from Wheaton College and his M.B.A. from The Tuck School of Business at Dartmouth College.

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 S.A., a global biopharmaceutical company, 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 wholly-owned subsidiary of Otsuka Pharmaceutical Company, Ltd., since June 2017. Mr. DesRosier earned a B.A. in Chemistry from the University of Vermont and a J.D. from Wake Forest University School of Law.

David S. Ege, Ph.D. has served as our Executive Vice President and Chief Technology Officer since October 2020. Previously, Dr. Ege served in a variety of technical and leadership roles in R&D and manufacturing at Merck from November 2003 to October 2020, most recently as global lead for digital strategy in Merck’s Manufacturing Division from June 2019 to October 2020. From April 2015 to June 2019, Dr. Ege served as Executive Director of Vaccines & Biologics Manufacturing at Merck’s plant in Elkton, Virginia, where he led bulk manufacturing operations for Gardasil®, Gardasil9® and Cancidas®. He has contributed to the successful first-in-class licensure and launch of cervical cancer vaccines, Gardasil® (2006) and Gardasil9® (2014), and a breakthrough cancer immunotherapy, Keytruda® (2014). He graduated summa cum laude from Princeton with a B.S.E. in chemical engineering and earned his Ph.D. in chemical engineering from the University of Pennsylvania.

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

Lisa von Moltke, M.D. has served as our Executive Vice President and Chief Medical Officer since March 2020. Previously, Dr. von Moltke worked for Alkermes, Inc., a pharmaceutical company, from June 2015 to December 2019, where she served in roles of increasing seniority, culminating as Senior Vice President and Head of Clinical Development. Beginning in June 2015, Dr. Moltke served as VP Clinical Pharmacology, DMPK and Bioanalytics, was promoted to Head of Clinical Development in November 2015, and became SVP in June 2018. Prior to joining Alkermes, Dr. von Moltke served as Vice President Clinical Pharmacology at Sanofi/Genzyme Corporation, a biotechnology company, from 2009 to 2015 and was US Head Clinical & Exploratory Pharmacology Sciences (CEP) and Early Development. Starting in 2014 she was Head CEP for Japan and China regions. From 2006 to 2009, Dr. von Moltke was Head, Translational Medicine for the Takeda Oncology Company, a biopharmaceutical company, in Cambridge, MA. 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 & Media" 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 information in response to this item is contained in part under the captions, "Directors of the Registrant" and "Information about our Executive Officers" at the end of Part I of this Annual Report on Form 10-K. 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 scheduled to be held on June 16, 2021 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 scheduled to be held on June 16, 2021 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 scheduled to be held on June 16, 2021 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 scheduled to be held on June 16, 2021 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 scheduled to be held on June 16, 2021 and is incorporated herein by reference.

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			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Amended and Restated By-Laws	8-K	001-37465	3.2	12/7/20	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-204484	4.2	6/16/15	
4.2	Description of Capital Stock					*
10.1#	2015 Incentive Award Plan and forms of award agreements thereunder					*
10.2#	2015 Employee Stock Purchase Plan	S-1/A	333-204484	10.3	6/16/15	
10.3#	2012 Stock Incentive Plan, as amended and form of option agreement thereunder	S-1	333-204484	10.1	5/27/15	
10.4#	Non-Employee Director Compensation Program					*
10.5	Lease Agreement, dated April 1, 2015, by and between the Registrant and ARE-MA Region No. 38, LLC	S-1	333-204484	10.13	5/27/15	
10.6	Lease, dated November 11, 2015, by and between the Registrant and BMR-Sidney Research Campus, LLC	10-K	001-37465	10.13	3/14/16	
10.7	Sublease Agreement dated July 1, 2019, by and between the Registrant and Flagship VL56, Inc., and Flagship VL58, Inc.	10-Q	001-37465	10.3	11/5/19	
10.8#	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	
10.9#	Employment Agreement, dated January 29, 2021 by and between the Registrant and Thomas J. DesRosier	8-K	001-37465	10.2	2/1/21	
10.10#	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	
10.11#	Employment Agreement, dated July 11, 2019, by and between the Registrant and Marcus Chapman	10-Q	001-37465	10.1	11/5/19	
10.12#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and David S. Ege, Ph.D.					*

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed/ Furnished Herewith
		Form	File No.	Exhibit	
10.13#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Teresa L. Young				*
10.14#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Lisa von Moltke, M.D.				*
10.15	Loan and Security Agreement, dated October 29, 2019, between the Registrant and Hercules Capital, Inc.	8-K	001-37465	10.1	11/4/19
10.16	First Amendment to Loan and Security Agreement by and between the Registrant and Hercules Capital, Inc., dated April 16, 2020	10-Q	001-37465	10.2	7/28/20
10.17^	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
10.18	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
10.19^	Letter Agreement dated October 30, 2018, by and between the Registrant and Nestec Ltd.	10-K	001-37465	10.23	3/6/19
10.20	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
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 Principal Financial Officer				*
32.1	Section 1350 Certification of Chief Executive Officer				**
32.2	Section 1350 Certification of Principal Financial Officer				**
101.INS	Inline XBRL Instance Document- the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document				*
101.SCH	Inline XBRL Taxonomy Extension Schema Document				*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				*

- * Filed herewith.
- ** Furnished herewith.
- # Indicates management contract or compensatory plan.
- ^ Confidential treatment has been granted with respect to redacted portions of this exhibit. Redacted portions of this exhibit have been filed separately with the SEC.

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 2, 2021

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
<u>/s/ Eric D. Shaff</u> Eric D. Shaff	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2021
<u>/s/ Marcus Chapman</u> Marcus Chapman	Vice President, Finance (Principal Financial and Accounting Officer)	March 2, 2021
<u>/s/ Stephen Berenson</u> Stephen Berenson	Chairman of the Board	March 2, 2021
<u>/s/ Dennis A. Ausiello</u> Dennis A. Ausiello, M.D.	Director	March 2, 2021
<u>/s/ Paul R. Biondi</u> Paul R. Biondi	Director	March 2, 2021
<u>/s/ Willard H. Dere</u> Willard H. Dere	Director	March 2, 2021
<u>/s/ Grégory Behar</u> Grégory Behar	Director	March 2, 2021
<u>/s/ Kurt C. Graves</u> Kurt C. Graves	Director	March 2, 2021
<u>/s/ Richard N. Kender</u> Richard N. Kender	Director	March 2, 2021
<u>/s/ Meryl S. Zausner</u> Meryl S. Zausner	Director	March 2, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2020 and 2019	F-4
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020, 2019 and 2018	F-5
Consolidated Statements of Stockholders' Equity (Deficit) as of December 31, 2020, 2019 and 2018	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018	F-7
Notes to Consolidated Financial Statements	F-8

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, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

Changes in Accounting Principles

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019 and the manner in which it accounts for revenues from contracts with customers in 2018.

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.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company will require additional financing to fund future operations. Management’s evaluation of the events and conditions and management’s plans to mitigate these matters are described in Note 1.

Critical Audit Matters

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

Revenue Recognition - Nestlé Health Science (‘NHS’) Collaboration Agreement Recognized Under an Input Method

As described in Notes 2 and 12 to the consolidated financial statements, the Company recognizes revenue arising from a collaboration agreement with NHS, which totaled \$11.9 million for the year ended December 31, 2020. The promised goods and services represent one combined performance obligation and the entire transaction price was allocated to that single combined performance obligation.

When management concludes that a contract should be accounted for as a combined performance obligation and recognized over-time, management must then determine the period over which revenue should be recognized and the method by which to measure revenue. Management generally recognizes revenue using a cost-based input method, which measures the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the performance obligation. Due to the nature of the work required to be performed to satisfy the performance obligation, management's estimation of costs expected is complex and requires significant judgment.

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

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

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 2, 2021

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,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 116,049	\$ 65,126
Short term investments	137,567	29,690
Prepaid expenses and other current assets	5,774	3,588
Accounts receivable	9,387	1,785
Total current assets	268,777	100,189
Property and equipment, net	13,897	19,495
Operating lease assets	9,041	11,356
Restricted investments	1,400	1,400
Long term investments	49,825	—
Total assets	\$ 342,940	\$ 132,440
Liabilities and Stockholder's Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 4,018	\$ 4,859
Accrued expenses and other current liabilities	14,226	10,884
Operating lease liabilities	5,115	4,456
Short term portion of note payable, net of discount	454	—
Deferred revenue - related party	22,602	20,960
Deferred revenue	—	4,834
Total current liabilities	46,415	45,993
Long term portion of note payable, net of discount	24,639	24,648
Operating lease liabilities, net of current portion	10,561	15,676
Deferred revenue, net of current portion - related party	85,572	89,111
Deferred revenue, net of current portion	—	4,834
Other long-term liabilities	1,003	502
Total liabilities	168,190	180,764
Commitments and contingencies (Note 14)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2020 and 2019; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at December 31, 2020 and 2019; 91,459,239 and 70,143,252 shares issued and outstanding at December 31, 2020 and 2019	91	70
Additional paid-in capital	723,482	411,255
Accumulated other comprehensive loss	(47)	—
Accumulated deficit	(548,776)	(459,649)
Total stockholders' equity (deficit)	174,750	(48,324)
Total liabilities and stockholders' equity (deficit)	\$ 342,940	\$ 132,440

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,		
	2020	2019	2018
Revenue:			
Collaboration revenue - related party	\$ 11,897	\$ 27,188	\$ 26,917
Grant revenue	4,157	1,102	1,350
Collaboration revenue	17,161	6,215	—
Total revenue	33,215	34,505	28,267
Operating expenses:			
Research and development expenses	\$ 90,570	\$ 80,141	\$ 95,955
General and administrative expenses	30,775	24,748	32,596
Restructuring expenses	—	1,492	—
Total operating expenses	121,345	106,381	128,551
Loss from operations	(88,130)	(71,876)	(100,284)
Other (expense) income:			
Interest income	946	1,033	1,172
Interest expense	(2,924)	(502)	—
Other income	981	1,066	170
Total other (expense) income, net	(997)	1,597	1,342
Net loss	\$ (89,127)	\$ (70,279)	\$ (98,942)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.12)	\$ (1.24)	\$ (2.43)
Weighted average common shares outstanding, basic and diluted	79,789,220	56,649,220	40,743,492
Other comprehensive (loss) income:			
Unrealized (loss) gain on investments, net of tax of \$0	(47)	—	146
Total other comprehensive income (loss)	(47)	—	146
Comprehensive loss	\$ (89,174)	\$ (70,279)	\$ (98,796)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Par Value				
Balance at December 31, 2017	40,571,015	\$ 40	\$ 324,376	\$ (146)	\$ (263,571)	\$ 60,699
Issuance of common stock upon exercise of stock options	212,240	1	146	—	—	147
Issuance of common stock upon vesting of RSUs, net of tax withholdings	138,048	—	61	—	—	61
Repurchase of common stock for employee tax withholdings	(17,900)	—	(197)	—	—	(197)
Issuance of common stock under ESPP plan	33,332	—	257	—	—	257
Stock-based compensation expense	—	—	16,641	—	—	16,641
Unrealized gain on investments	—	—	—	146	—	146
Adoption of new revenue standard (ASC 606)	—	—	—	—	(26,857)	(26,857)
Net loss	—	—	—	—	(98,942)	(98,942)
Balance at December 31, 2018	<u>40,936,735</u>	<u>41</u>	<u>341,284</u>	<u>—</u>	<u>(389,370)</u>	<u>(48,045)</u>
Issuance of common stock from public offering, net of commissions, underwriting discounts and offering costs	28,818,578	29	60,498	—	—	60,527
Issuance of common stock from at the market equity offering	128,400	—	512	—	—	512
Issuance of common stock upon exercise of stock options	90,125	—	145	—	—	145
Issuance of common stock upon vesting of RSUs, net of tax withholdings	94,400	—	176	—	—	176
Issuance of common stock under ESPP plan	75,014	—	296	—	—	296
Stock-based compensation expense	—	—	8,344	—	—	8,344
Net loss	—	—	—	—	(70,279)	(70,279)
Balance at December 31, 2019	<u>70,143,252</u>	<u>70</u>	<u>411,255</u>	<u>—</u>	<u>(459,649)</u>	<u>(48,324)</u>
Issuance of common stock from public offering, net of commissions, underwriting discounts and offering costs	12,075,000	12	243,736	—	—	243,748
Issuance of common stock from Securities Purchase Agreement, net of offering costs - related party	959,002	1	19,899	—	—	19,900
Issuance of common stock from at the market equity offering	5,787,681	6	24,767	—	—	24,773
Issuance of common stock upon exercise of stock options	2,214,011	2	14,419	—	—	14,421
Issuance of common stock upon vesting of RSUs, net of tax withholdings	125,000	—	120	—	—	120
Issuance of common stock under ESPP plan	155,293	—	462	—	—	462
Stock-based compensation expense	—	—	8,824	—	—	8,824
Unrealized loss on investments	—	—	—	(47)	—	(47)
Net loss	—	—	—	—	(89,127)	(89,127)
Balance at December 31, 2020	<u>91,459,239</u>	<u>\$ 91</u>	<u>\$ 723,482</u>	<u>\$ (47)</u>	<u>\$ (548,776)</u>	<u>\$ 174,750</u>

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,		
	2020	2019	2018
Cash flows from operating activities:			
Net loss	\$ (89,127)	\$ (70,279)	\$ (98,942)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation expense	8,824	8,344	16,641
Depreciation and amortization expense	6,578	7,603	7,862
Non-cash operating lease cost	2,315	2,227	—
Amortization of debt issuance costs	446	281	—
Accretion (amortization) of discount (premium) on issued debt securities	551	(172)	(214)
Loss on disposal of property and equipment	—	103	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(2,186)	3,257	(2,056)
Accounts receivable	(7,602)	(1,785)	—
Deferred revenue	(11,565)	(17,520)	13,476
Accounts payable	(1,159)	(1,460)	(353)
Operating lease liabilities	(4,456)	(4,211)	—
Accrued expenses and other liabilities	3,771	(2,908)	732
Net cash (used in) operating activities	<u>(93,610)</u>	<u>(76,520)</u>	<u>(62,854)</u>
Cash flows from investing activities:			
Purchases of property and equipment	(591)	(1,002)	(1,937)
Purchases of investments	(218,284)	(46,420)	(21,832)
Sales and maturities of investments	59,984	16,904	136,087
Net cash (used in) provided by investing activities	<u>(158,891)</u>	<u>(30,518)</u>	<u>112,318</u>
Cash flows from financing activities:			
Proceeds from public offering of common stock, net of commissions, underwriting discounts and offering costs	243,748	60,527	—
Proceeds from Securities Purchase Agreement, net of issuance costs - related party	19,900	—	—
Proceeds from issuance of note payable	—	25,000	—
Proceeds from at the market equity offering, net of commissions	24,773	512	—
Payments of debt issuance costs	—	(425)	—
Proceeds from exercise of stock options	14,421	145	147
Proceeds from issuance of common stock and restricted common stock	120	176	61
Payments for repurchase of common stock for employee tax withholdings	—	—	(197)
Issuance of common stock under ESPP plan	462	296	257
Net cash provided by financing activities	<u>303,424</u>	<u>86,231</u>	<u>268</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	50,923	(20,807)	49,732
Cash, cash equivalents and restricted cash at beginning of year	65,126	85,933	36,201
Cash, cash equivalents and restricted cash at end of year	<u>\$ 116,049</u>	<u>\$ 65,126</u>	<u>\$ 85,933</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 2,453	\$ 221	\$ —
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment purchases included in accounts payable and accrued expenses	\$ 451	\$ 62	\$ 157
Reduction of operating lease assets and operating lease liabilities from operating lease modifications or reassessments	—	154	—

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 microbiome therapeutics platform company developing a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. The Company’s lead product candidate, SER-109, is designed to prevent further recurrences of *Clostridioides difficile* infection (“CDI”), a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by treating the disruption of the colonic microbiome. If approved by the U.S. Food and Drug Administration (“FDA”), we believe SER-109 will be a first-in-field oral microbiome drug. SER-287 and SER-301 are being developed by the Company to treat ulcerative colitis (“UC”). In addition, using its microbiome therapeutics platform, the Company is also developing product candidates to treat diseases where the microbiome is implicated, including SER-155, a consortium of cultivated bacteria, therapeutics candidate designed to prevent mortality due to gastrointestinal infections, bacteremia and graft versus host disease (GvHD) in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation (“allo-HSCT”) and solid organ transplants and SER-401, a microbiome therapeutics candidate for use with checkpoint inhibitors (CPI’s”) in patients with metastatic melanoma. The Company continues to evaluate microbiome pharmacokinetic of SER-262 to treat an initial recurrence of CDI. The Company is also using its reverse translation microbiome therapeutics platforms to conduct research on various indications, including pathogen infection and antibiotic resistant bacteria, inflammatory and immune diseases, cancer, and metabolic diseases.

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. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

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

On August 10, 2020, the Company reported positive topline results from its pivotal Phase 3 ECOSPOR III study evaluating SER-109 for recurrent CDI. The Company is actively enrolling patients in its SER-109 open-label study, which also admits patients with a single recurrence of CDI, to expand the safety database to meet the FDA threshold of at least 300 patients.

On August 12, 2020, the Company completed an underwritten public offering in which it sold 10,500,000 shares of its common stock at a public offering price of \$21.50 per share. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 1,575,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. The Company received aggregate net proceeds from the offering of approximately \$243,748 after deducting underwriting discounts and commissions and offering expenses payable by the Company.

On August 12, 2020, the Company entered into a Securities Purchase Agreement (the “Securities Agreement”) with Société des Produits Nestlé S.A. (“Nestlé”) for the sale of 959,002 shares of its common stock at a purchase price of \$20.855 per share (the “concurrent placement”). The Company received aggregate net proceeds from the concurrent placement of approximately \$19,900 after deducting offering expenses payable by the Company.

Under Accounting Standards Update (“ASU”) 2014-15, *Presentation of Financial Statements—Going Concern* (Subtopic 205-40) (“ASC 205-40”), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. As required by ASC 205-40, this evaluation shall initially not take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued.

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

As of December 31, 2020, the Company had an accumulated deficit of \$548,776 and cash, cash equivalents and short- and long-term investments of \$303,441. For the year ended December 31, 2020, the Company incurred a loss of \$89,127 and used \$93,610 of cash in operations. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. The Company expects that its cash, cash equivalents and short and long-term investments as of December 31, 2020 of \$303,441 will be sufficient to fund its operating expenses, capital expenditure requirements, and debt service obligations for at least the next 12-months from issuance of the financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is eligible to receive contingent milestone payments under its license and collaboration agreement with Société des Produits Nestlé S.A. (“Nestlé”), successor in interest to Nestec Ltd., an affiliate of Nestlé Health Science US Holdings, Inc. (“Nestlé Health Science”), both of which are significant stockholder of the Company, if certain development milestones are achieved. However, these milestones are uncertain and there is no assurance that the Company will receive any of them. Until such time, if ever, as the Company can generate substantial product revenue, the Company will finance its cash needs through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. The Company may not be able to obtain funding on acceptable terms, or at all. If the Company is unable to raise additional funds as and when needed, it would have a negative impact on the Company’s financial condition, which may require the Company to delay, reduce or eliminate certain research and development activities and reduce or eliminate discretionary operating expenses, which could constrain the Company’s ability to pursue its business strategies.

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 expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited 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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company’s business, results of operations and financial condition, including revenue, operating expenses, clinical trials and employee-related amounts, will depend on future developments that are highly uncertain, including new information that may emerge concerning COVID-19 and the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. 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 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.

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 income (loss) in stockholders’ equity (deficit). The cost of securities sold is determined on a specific identification

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

basis, and realized gains and losses are included in other income (expense) within the consolidated statement of operations and comprehensive loss. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be “other than temporary”, the Company reduces the investment to fair value through a charge to the consolidated statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Restricted Investments

The Company held investments of \$1,400 as of December 31, 2020 and December 31, 2019 in a separate restricted bank account as a security deposit for the lease of the Company’s facilities. The Company has classified these deposits as long-term restricted investments on its balance sheet.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, 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.

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

Fair Value Measurements

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

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

The Company’s cash equivalents 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 accounts receivable, prepaid expense and other current assets, accounts payable and accrued expenses approximates their fair value due to the short-term nature of these assets and liabilities. The carrying value of the Company’s long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

Property and Equipment

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

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

Impairment of Long-Lived Assets

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

Research and Development Costs

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

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued 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 lacks sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The Company uses the simplified method

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

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 adopted ASC 606 on January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption.

Under ASC 606, the Company recognizes revenue using the cost-to-cost method over the remaining performance period as described in Note 12. The cumulative effect of applying ASC 606 as of the adoption date of January 1, 2018 of \$26,857 was recorded as an adjustment to accumulated deficit in the statement of stockholders' equity (deficit).

The Company recognizes 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. 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:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) 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.

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

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. As of December 31, 2020 and December 31, 2019, the Company had \$1,186 and \$406 of accounts receivable and \$8,201 and \$1,379 of unbilled accounts receivable, respectively.

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

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

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.

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 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.

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

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, 2020, 2019 and 2018, other comprehensive income (loss) consisted of changes in unrealized gains (losses) from available-for-sale investments.

Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and unvested restricted stock. The Company applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a net loss position for each of the periods presented.

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

Leases

The Company adopted ASC 842 on January 1, 2019 using the modified retrospective approach with no restatement of prior periods or cumulative adjustment to accumulated deficit. The Company determined if an arrangement is a lease at contract inception based on the facts and circumstances present in the arrangement. All the Company's leases are classified as operating leases under the new leasing standard. The Company records operating lease assets and lease liabilities in its consolidated balance sheets. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the leasing arrangement. Operating lease assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, in determining the operating lease liabilities, the Company uses an estimate of its incremental borrowing rate based on the information available at commencement. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Short-term leases, or leases that have a lease term of 12 months or less at commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease.

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

Recently Adopted Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* (“ASU 2018-18”). This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, Revenue from Contracts with Customers, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Precludes a company from presenting transactions with collaborative participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

This standard became effective for the Company on January 1, 2020 and did not have a material impact on the Company’s consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”). This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for the Company on January 1, 2020 and did not have a material impact on the Company’s disclosures.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* (“ASU 2019-05”). ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. This standard will be effective for the Company on January 1, 2023. The Company is currently evaluating the potential impact that this standard may have on its condensed consolidated financial statements and related disclosures.

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, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Cash Equivalents:				
Money market funds	\$ 35,480	\$ —	\$ —	\$ 35,480
Commercial paper	—	10,313	—	10,313
Corporate bonds	—	2,014	—	2,014
Investments:				
Commercial paper	\$ —	\$ 12,343	\$ —	\$ 12,343
Corporate bonds	—	68,289	—	68,289
Certificate of deposits	—	2,272	—	2,272
Government securities	—	104,488	—	104,488
	<u>\$ 35,480</u>	<u>\$ 199,719</u>	<u>\$ —</u>	<u>\$ 235,199</u>

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

	Fair Value Measurements as of December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Cash Equivalents:				
Money market funds	\$ 25,510	\$ —	\$ —	\$ 25,510
Commercial paper	—	4,243	—	4,243
Corporate bonds	—	4,900	—	4,900
Investments:				
Commercial paper	\$ —	\$ 11,957		\$ 11,957
Corporate bonds	—	17,733		17,733
	<u>\$ 25,510</u>	<u>\$ 38,833</u>	<u>\$ —</u>	<u>\$ 64,343</u>

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Commercial paper, government securities, certificates of deposit and corporate bonds were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. There were no transfers between Level 1 or Level 2 during the years ended December 31, 2020 and 2019.

As of December 31, 2020 and 2019 the Company held a restricted investment of \$1,400, which represents a certificate of deposit that is classified as Level 2 in the fair value hierarchy.

4. Investments

Investments by security type consisted of the following at December 31, 2020 and December 31, 2019 (in thousands):

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	\$ 12,343	\$ —	\$ —	\$ 12,343
Corporate bonds	68,333	8	(52)	68,289
Certificate of deposits	2,272	-	-	2,272
Government securities	104,491	6	(9)	104,488
	<u>\$ 187,439</u>	<u>\$ 14</u>	<u>\$ (61)</u>	<u>\$ 187,392</u>
	December 31, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	\$ 11,957	\$ —	\$ —	\$ 11,957
Corporate bonds	17,732	3	(2)	17,733
	<u>\$ 29,689</u>	<u>\$ 3</u>	<u>\$ (2)</u>	<u>\$ 29,690</u>

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

Excluded from the table above is a restricted investment of \$1,400 as the cost approximates current fair value.

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

The amortized cost and fair value of investments in commercial paper, corporate bonds, certificates of deposit and government securities by contractual maturity, as of December 31, 2020 were as follows (in thousands):

	Available-for-Sale	
	Cost	Fair Value
Due in 1-year or less	\$ 137,588	\$ 137,567
Due after 1-year through 5-years	49,851	49,825
	<u>\$ 187,439</u>	<u>\$ 187,392</u>

As of December 31, 2019, we did not hold any investments with a contractual maturity over one year.

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2020	2019
Laboratory equipment	\$ 15,985	\$ 15,140
Computer equipment	2,874	2,874
Furniture and office equipment	1,033	1,033
Leasehold improvements	27,977	27,977
Construction in progress	348	213
	<u>48,217</u>	<u>47,237</u>
Less: Accumulated depreciation and amortization	(34,320)	(27,742)
	<u>\$ 13,897</u>	<u>\$ 19,495</u>

Depreciation and amortization expense was \$6,578, \$7,603 and \$7,862 for the years ended December 31, 2020, 2019 and 2018, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2020	2019
Development and clinical manufacturing costs	\$ 6,339	\$ 5,605
Payroll and payroll-related costs	6,734	4,609
Facility and other	1,153	670
	<u>\$ 14,226</u>	<u>\$ 10,884</u>

7. Leases

The Company adopted ASC 842 on January 1, 2019 using the modified retrospective approach with no restatement of prior periods or cumulative adjustment to accumulated deficit. The reported results for 2019 and 2020 reflect the application of ASC 842 while the reported results for 2018 were prepared under ASC 840.

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from less than 1 year to 3 years. Certain leases include one or more options to renew, exercised at the Company's sole discretion, with renewal terms that can extend the lease from one year to five years. The Company evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised, and therefore should be included in the calculation of the operating lease assets and operating lease liabilities. 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.

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

In July 2019, the Company entered into a sublease agreement with a related party to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in July 2019 and ends on the last day of the 24th calendar month following commencement, with no option to extend. The annual rent for the subleased premises will be approximately \$1,200 in the first year and \$1,300 in the second year, which is greater than the annual rent owed by the Company to the landlord for the leased premises. 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.

As of December 31, 2020, future undiscounted cash inflows under the sublease are as follows:

<u>Year Ending December 31,</u>		
2021	\$	633
Total	\$	<u>633</u>

The Company concluded that the sublease is an operating lease. Consistent with the Company's policy election for lessor operating leases, each lease component and its associated non-lease components is accounted for as a single lease component.

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

	<u>As of December 31,</u> <u>2020</u>	<u>As of December 31,</u> <u>2019</u>
<i>Assets:</i>		
Operating lease assets	\$ 9,041	\$ 11,356
<i>Liabilities:</i>		
Operating lease liabilities	\$ 5,115	\$ 4,456
Operating lease liabilities, net of current portion	10,561	15,676
Total operating lease liabilities	<u>\$ 15,676</u>	<u>\$ 20,132</u>

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

	<u>For the Year Ended</u> <u>December 31, 2020</u>	<u>For the Year Ended</u> <u>December 31, 2019</u>
Operating lease costs	\$ 4,163	\$ 4,532
Short-term lease costs	1,457	1,878
Variable lease costs	2,890	3,022
Sublease income	(1,813)	(890)
Total lease costs	<u>\$ 6,697</u>	<u>\$ 8,542</u>

During the year ended December 31, 2018, the Company recognized \$4,377 of rental expense related to office, laboratory, and manufacturing space. During the years ended December 31, 2020 and December 31, 2019, the Company made cash payments of \$6,302 and \$6,514 for operating leases, respectively.

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

As of December 31, 2020, future payments of operating lease liabilities are as follows (in thousands):

	<u>As of December 31, 2020</u>
2021	6,461
2022	6,390
2023	5,158
2024	—
2025 and thereafter	—
Total future payments of operating lease liabilities	\$ 18,009
Less: imputed interest	(2,333)
Present value of operating lease liabilities	<u>\$ 15,676</u>

As of December 31, 2020, the weighted average remaining lease term was 2.89 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 11%. As of December 31, 2019, the weighted average remaining lease term was 3.88 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 11%.

8. Restructuring

In February 2019, the Company implemented corporate changes to focus its resources on advancing its clinical-stage therapeutic candidates. As a result, the Company is concentrating on completing the SER-287 Phase 2b study in mild-to-moderate UC, expanding the SER-109 safety database to meet the FDA threshold of at least 300 patients, advancing the SER-401 Phase 1b study, to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma and advancing SER-301 into clinical development. In connection with the prioritization of these therapeutic candidates, the Company made changes to its management team and reduced headcount by approximately 30 percent.

During the year ended December 31, 2019 the Company recorded charges of \$1,492, related to severance and other termination benefits. No restructuring charges were recorded during the years ended December 31, 2020 and 2018. During the year ended December 31, 2019 the Company paid \$1,299 related to the restructuring and paid out the remaining \$193 in 2020.

During the year ended December 31, 2019, the Company paid \$1,299 related to the restructuring. The outstanding restructuring liabilities are included in accrued expenses and other current liabilities on the consolidated balance sheets as of December 31, 2019. As of December 31, 2019, the components of the outstanding restructuring liabilities included in accrued expenses and other current liabilities were as follows:

	<u>Employee Severance and Other Benefits</u>
Restructuring expenses	\$ 1,492
Cash payments	(1,299)
Liability included in accrued expenses and other current liabilities at December 31, 2019	<u>\$ 193</u>

During the year ended December 31, 2020, the Company made the remaining cash payments of \$193. There were no outstanding restructuring liabilities included in accrued expenses and other current liabilities as of December 31, 2020.

9. Notes Payable

On October 29, 2019 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules") pursuant to which a term loan in an aggregate principal amount of up to \$50,000 (the "Term Loan Facility") is available to the Company in three tranches, subject to certain terms and conditions. The first tranche of \$25,000 was advanced to the Company on the Closing Date. The Company did not meet the milestone requirements for the second tranche under the Term Loan Facility, and as such, the additional amount up to \$12,500 is not available for the Company to borrow. The third tranche, which allows the Company to borrow an additional \$12,500, will be available upon Hercules' approval on or prior to June 30, 2021.

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

Advances under the Term Loan Facility will bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.40%, and (ii) 9.65%. The Company will make interest only payments through December 1, 2021. The interest only period may be extended to June 1, 2022 upon satisfaction of certain milestones. Following the interest only period, the Company will repay the principal balance and interest of the advances in equal monthly installments through November 1, 2023.

The Company may prepay advances under the Loan Agreement, in whole or in part, at any time subject to a prepayment charge (the “Prepayment Premium”) equal to: (a) 3.0 % of amounts so prepaid, if such prepayment occurs during the first year following the Closing Date; (b) 2.0% of the amount so prepaid, if such prepayment occurs during the second year following the Closing Date, and (c) 1.0% of the amount so prepaid, if such prepayment occurs after the second year following the Closing Date.

Upon prepayment or repayment of all or any of the term loans under the Term Loan Facility, the Company will pay (in addition to any Prepayment Premium) an end of term charge of 4.85% of the aggregate funded amount under the Term Loan Facility. With respect to the first tranche, an end of term charge of \$1,213 will be payable upon any prepayment or repayment. To the extent that the Company is provided additional advances under the Term Loan Facility, the 4.85% end of term charge will be applied to any such additional amounts.

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

Upon issuance, the first tranche was recorded as a liability with an initial carrying value of \$24,575, net of debt issuance costs. The initial carrying value will be accreted to the repayment amount, which includes the outstanding principal plus the end of term charge, through interest expense using the effective interest rate method over the term of the debt. The effective interest rate is 11.47%. As of December 31, 2020, the carrying value of the debt is \$25,093, of which \$454 is classified as a current liability and \$24,639 is classified as a non-current liability on the Company’s consolidated balance sheet.

As of December 31, 2020, the future principal payments due under the arrangement, excluding interest and the end of term charge, are as follows:

<u>Year Ending December 31,</u>	<u>Principal</u>
2021	949
2022	11,970
2023	12,081
Total	<u>\$ 25,000</u>

During the years ended December 31, 2020 and December 31, 2019, the Company recognized \$2,899 and \$502 of interest expense related to the Loan Agreement, respectively, which is reflected in other income (expense), net on the consolidated statements of operations and comprehensive loss.

10. Convertible Preferred Stock

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

11. Stockholders’ Equity Common Stock

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 June 18, 2019, the Company completed an underwritten public offering, in which the Company sold 26,666,667 shares of its common stock at a price to the public of \$2.25 per share. The aggregate net proceeds received by the Company from the offering were approximately \$55,976, after deducting underwriting discounts and commissions and offering expenses payable by the Company. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 2,666,666 shares of common stock at the public offering price, less underwriting discounts and commissions.

On June 21, 2019, the Company sold an additional 2,151,911 shares of its common stock at a price to the public of \$2.25 per share. The aggregate net proceeds received by the Company were approximately \$4,551, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

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

On November 27, 2019, the Company entered into a Sales Agreement (the “2019 Sales Agreement”) with Cowen and Company, LLC (“Cowen”) to sell shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), with aggregate gross sales proceeds of up to \$25,000, from time to time, through an “at the market” equity offering program under which Cowen will act as sales agent. On March 18, 2020, in connection with filing an updated registration statement on Form S-3 (File No. 333-237033), the Company entered into a Sales Agreement (the “2020 Sales Agreement”), with Cowen on substantially the same terms as the 2019 Sales Agreement and terminated the 2019 Sales Agreement. From January 1, 2020 to December 31, 2020 the Company sold 5,787,681 shares of common stock under the 2019 Sales Agreement and the 2020 Sales Agreement, as applicable, at an average price of approximately \$4.40 per share, raising aggregate net proceeds of approximately \$24,773 after deducting an aggregate commission of approximately 3%.

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

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

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, 2020, 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 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, cancelled, 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 options 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, 2020, there were 1,018,232 shares available for future grant under the 2015 Plan.

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

2015 Employee Stock Purchase Plan

On June 16, 2015, the Company's stockholders approved the 2015 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 25, 2015. A total of 365,000 shares of common stock were reserved for issuance under the ESPP. In addition, the number of shares of common stock that may be issued under the ESPP automatically increase on the first day of each calendar year, beginning in 2016 and ending in 2025, by an amount equal to the lesser of (i) 400,000 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the last day of the applicable preceding calendar year and (iii) an amount determined by the Company's board of directors. Offering periods under the ESPP will commence when determined by the plan administrator. As of December 31, 2020, there were 155,293 shares issued under the ESPP and 2,092,181 shares were reserved and available for issuance under the ESPP.

The ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock. The ESPP is qualified under Section 423 of the Internal Revenue Code. The employee's purchase price is derived from a formula based on the closing price of the common stock on the first day of the offering period versus the closing price on the date of purchase (or, if not a trading day, on the immediately preceding trading day). The offering period under the ESPP has a duration of six months, and the purchase price with respect to each offering period beginning on or after such date is, until otherwise amended, equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month offering period or (ii) the fair market value of the Company's common stock on the purchase date. The Company estimates the fair value of common stock under the ESPP using a Black-Scholes valuation model. The fair value was estimated on the date of grant using the Black-Scholes option valuation model and the straight-line attribution approach with the following weighted-average assumptions: risk-free interest rate (1.2%); expected term (0.5 years); expected volatility (74.9%); and an expected dividend yield (0%). The Company recorded \$200, \$109 and \$145 of stock-based compensation expense under the ESPP for the twelve months ended December 31, 2020, 2019 and 2018, respectively.

Stock Option Valuation

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

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	1.26%	2.64%	2.39%
Expected term (in years)	6.0	6.0	6.0
Expected volatility	73.3%	88.4%	76.0%
Expected dividend yield	0%	0%	0%

Stock Options

The following table summarizes the Company's stock option activity for the twelve months ended December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	8,310,683	\$ 10.36	7.01	\$ 3,427
Granted	5,095,365	7.11		
Exercised	(2,214,011)	6.51		
Forfeited	(1,154,907)	10.50		
Outstanding as of December 31, 2020	<u>10,037,130</u>	\$ 9.54	7.87	\$ 156,627
Options exercisable as of December 31, 2020	<u>3,164,129</u>	\$ 14.70	5.75	\$ 34,652

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2020, 2019 and 2018 was \$5.08, \$4.13, and \$6.53 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2020, 2019, and 2018 was \$37,255, \$244, and \$1,801, respectively.

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

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

During the year ended December 31, 2019, the Company granted performance-based stock options to employees for the purchase of an aggregate of 1.1 million shares of common stock with a grant date fair value of \$4.58 per share. These stock options are exercisable only upon achievement of specified performance targets. As of December 31, 2020, none of these options were exercisable because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of December 31, 2020, the Company did not record any expense for these stock options from the dates of issuance through December 31, 2020.

Restricted Stock Units

The Company has granted restricted stock units with time-based vesting conditions. The table below summarizes the Company's restricted stock activity for the twelve months ended December 31, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2019	130,000	\$ 8.86
Granted	6,500	\$ 25.36
Forfeited	(5,000)	\$ 9.12
Vested	(125,000)	\$ 2.29
Unvested restricted stock units as of December 31, 2020	<u>6,500</u>	<u>\$ 25.36</u>

The aggregate intrinsic value of restricted stock units that vested during the years ended December 31, 2020, 2019 and 2018 was \$532, \$517, and \$1,206, respectively.

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,		
	2020	2019	2018
Research and development expenses	\$ 4,760	\$ 4,613	\$ 8,388
General and administrative expenses	4,064	3,731	8,253
	<u>\$ 8,824</u>	<u>\$ 8,344</u>	<u>\$ 16,641</u>

As of December 31, 2020, the Company had an aggregate of \$26,221 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.49 years.

12. Collaboration Revenue

Nestlé Collaboration Agreement

Summary of Agreement

In January 2016, the Company entered into the License Agreement 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. The 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 "Licensed Territory"). The Company has retained full commercial rights to its entire portfolio of product candidates with respect to the United States and Canada.

Under the License Agreement, the Company granted to Nestlé an exclusive, royalty-bearing license to develop and commercialize, in the Licensed Territory, certain products based on its microbiome technology that are being developed for the

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

treatment of CDI and IBD, including SER-109, SER-262, SER-287 and SER-301 (collectively, the “Nestlé Collaboration Products”). The License Agreement sets forth the Company’s and Nestlé’s respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the Nestlé Collaboration Products with respect to the licensed fields and the Licensed Territory.

Under the 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 Nestlé 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 Nestlé Collaboration Products in the Licensed Territory.

Under the License Agreement, the Company was 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 License Agreement to address the current clinical plans for SER-287. Through the letter agreement, the Company and Nestlé agreed that following initiation of the SER-287 Phase 2b study, the Company will receive \$40,000 in milestone payments from Nestlé which represents the milestone due to the Company for the initiation of the SER-287 Phase 2 and Phase 3 studies. The SER-287 Phase 2b study was initiated and the \$40,000 of milestone payments were received in December 2018. The letter agreement also provides scenarios under which Nestlé’s reimbursement to the Company for certain Phase 3 development costs would be reduced or delayed depending on the outcomes of the SER-287 Phase 2b study.

Accounting Analysis

The Company assessed the License Agreement in accordance with ASC 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 Nestlé Collaboration Products in the 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 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.

Therefore, as of December 31, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligation of the License Agreement was approximately \$200,000.

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. In the third quarter of 2018, the Company increased the transaction price by \$20,000 associated with the Phase 2 milestone for SER-287. The Company estimated the \$20,000 of variable consideration by using the most likely amount method which best predicts the amount of consideration to which the Company will be entitled. The Company included the \$20,000 in the transaction price because it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur when the uncertainty associated with the variable consideration was subsequently resolved.

In the fourth quarter of 2018, the Company entered into a letter agreement with Nestlé which modified the License Agreement to address the current clinical plans for SER-287. As a result of this modification, the Company and Nestlé agreed that the \$20,000

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

milestone payment due to the Company from Nestlé following the initiation of a Phase 3 study for SER-287 would now be due to the Company upon initiation of the SER-287 Phase 2b study. The Letter Agreement constituted a contract modification under ASC 606. The Company accounted for the contract modification through a cumulative catch-up adjustment of approximately \$5,517 because the contract modification did not add any additional goods or services and the remaining goods and services are not distinct. The SER-287 Phase 2b study was initiated in December 2018 and the Company included the \$20,000 in the transaction price as of December 31, 2018. The transaction price as of December 31, 2018 was approximately \$190,000.

In April 2019, the Company, with the approval of the Seres/ Nestlé Joint Steering Committee, as provided for in the License Agreement, modified the SER-109 clinical trial. As a result of this modification, the Company and Nestlé agreed, and informed the FDA, that the target study enrollment would be reduced from 320 subjects to 188 subjects. This modification to the SER-109 clinical trial constituted a contract modification under ASC 606. The Company accounted for the contract modification through a cumulative catch-up adjustment because the contract modification did not add any additional goods or services and the remaining goods and services are not distinct. The modification reduced the total estimated costs in the Company's cost-to-cost model for the License Agreement and resulted in the Company recognizing \$6,830 of collaboration revenue – related party in the twelve months ended December 31, 2019.

During the year ended December 31, 2020, the Company received \$10,000 from Nestlé in connection with the initiation of the Phase 1b study for SER-301. In the third quarter of 2020, the Company increased the transaction price by \$10,000 associated with the Phase 1b milestone for SER-301. The Company estimated the \$10,000 of variable consideration by using the most likely amount method which best predicts the amount of consideration to which the Company will be entitled. The Company included the \$10,000 in the transaction price because it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur when the uncertainty associated with the variable consideration was subsequently resolved. This resulted in \$4,565 of cumulative catch-up revenue during the twelve months ended December 31, 2020, which was primarily off-set by the Company's updated estimate of future costs that would be incurred from on-going research and development services to complete its performance obligation under the License Agreement that is recognized over time using the input method.

During the twelve months ended December 31, 2020, 2019, and 2018 using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized \$11,897, \$27,188, and \$26,917 of Collaboration revenue – related party, respectively.

As of December 31, 2020 and December 31, 2019, there was \$108,174, and \$110,071 of deferred revenue related to the unsatisfied portion of the performance obligation under the License Agreement. As of December 31, 2020, 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. Due to the nature of the work required to be performed to satisfy the performance obligation, the Company's estimation of costs expected is complex and requires significant judgment. All costs associated with the License Agreement are recorded in research and development expense in the consolidated statements of operations and comprehensive loss.

AstraZeneca Research Collaboration and Option Agreement

Summary of the Agreement

In March 2019, the Company entered into a Research Collaboration and Option Agreement (the "Research Agreement") with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc. ("AstraZeneca"), to advance the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy. Under the Research Agreement, the Company and AstraZeneca will conduct certain research and development activities as set forth on a research plan focused on the role of the microbiome in certain cancers and cancer immunotherapies, including furthering the research program for SER-401, in combination with AstraZeneca compounds targeting various cancers.

Pursuant to the Research Agreement, the Company agreed not to conduct research or development on any microbiome products specifically designed by the Company during the term of the Research Agreement for the treatment of cancer ("Microbiome Oncology Products"), with or on behalf of any third-party without the prior approval of the joint steering committee for the Research Agreement for at least three years after the effective date (the "Exclusivity Period"). Additionally, AstraZeneca will pay to the Company a total of \$20,000 in three equal installments, the first of which the Company received in April 2019, the second of which the Company received in December 2019, and the third of which the Company received in January 2021. Such payments are payable even if the

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

Research Agreement is terminated in accordance with its terms, unless the Research Agreement is terminated by AstraZeneca for the Company's uncured material breach. Additionally, AstraZeneca will bear its costs of conducting activities under the research plan and will reimburse the Company for all activities performed under the research plan based on actual full-time employee ("FTE") time and certain third-party costs incurred by the Company in connection therewith.

Under the Research Agreement, the Company granted to AstraZeneca an exclusive option to negotiate a worldwide, sublicensable exclusive license under relevant intellectual property rights controlled by the Company to exploit Microbiome Oncology Products for the treatment of cancer. Additionally, the Company granted to AstraZeneca an additional exclusive option to obtain a worldwide, sublicensable, license under certain intellectual property rights arising out of the Agreement or coming into the control of the Company during the term of the Agreement, to exploit AstraZeneca's oncology and other assets which are the subject of the research plan. AstraZeneca may exercise each option at any point prior to 90 days after the end of the Exclusivity Period (the "Option Exercise Period") by delivering an option exercise notice to the Company. If AstraZeneca exercises an option during the Option Exercise Period, the parties will enter into exclusive, good faith negotiations for a period of six months (the "Negotiation Period") regarding the terms of the definitive license agreement contemplated by such option. If no definitive agreement is reached during the Negotiation Period, subject to certain other terms and conditions applicable for a one (1) year period, the Company is free to license, further develop or otherwise exploit its assets that were the subject of the option without further obligation to AstraZeneca.

The term of the Research Agreement continues in effect until the Research Agreement is terminated by the parties in accordance with its terms by mutual written agreement. Either party may terminate the Research Agreement for the other party's uncured material breach or bankruptcy or insolvency-related events. AstraZeneca may terminate the Research Agreement for convenience. In December 2020, the Company received written notice from AstraZeneca that AstraZeneca elected to terminate the Research Agreement by and in accordance with its terms. The termination of the Research Agreement will be effective on April 2, 2021 (the "Termination Date"), which is 120 days from the date of the termination notice.

Accounting Analysis

The Company assessed the Research Agreement in accordance with ASC 606 and concluded that AstraZeneca is a customer. The Company identified the following promises under the contract: (i) a research license, (ii) an obligation to perform research and development services, and (iii) participation on a joint steering committee. The Company assessed the promised goods and services to determine if they are distinct. Based on this assessment, the Company determined that AstraZeneca 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.

Each exclusive option granted to AstraZeneca provides AstraZeneca with the right to negotiate a license agreement in the future at fair value. Therefore, the Company concluded that each option does not constitute a performance obligation at inception and has been excluded from the initial allocation since each option represents a separate buying decision at market rates, rather than a material right in the contract.

At contract inception, the Company determined that the transaction price is comprised of: (i) the \$20,000 fee, which represents fixed consideration, and (ii) the estimated reimbursement of research and development costs incurred, which represents variable consideration. The Company included the estimated reimbursement of research and development costs, approximately \$13,900, in the transaction price at the inception of the arrangement because the Company is required to perform research and development services and the contract requires AstraZeneca to reimburse the Company for costs incurred. Also, since the related revenue would be recognized only as the costs are incurred, and the contract precludes the joint steering committee from changing the research plan without mutual agreement, the Company determined it is not probable that a significant reversal of cumulative revenue would occur.

The Company determined that revenue under the Research Agreement should be recognized over time as AstraZeneca simultaneously receives the benefit from the Company as the Company performs under the single performance obligation over time. The Company will recognize revenue for the single performance obligation using a cost-to-cost input method as the Company has concluded it best depicts the research and joint steering committee participation services performed prior to AstraZeneca's ability to negotiate a license. Under this method, the transaction price is recognized over the contract's entire performance period, using costs incurred relative to total estimated costs to determine the extent of progress towards completion.

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

In December 2020, the Company received written notice that AstraZeneca elected to terminate the Research Agreement. As a result of AstraZeneca's decision to terminate the Research Agreement, the Company's performance obligations under the Research Agreement have ended as of December 31, 2020. The final transaction price of \$23,377 is comprised of the \$20,000 fixed consideration and \$3,376 for the reimbursed research and development costs. The Company removed all costs associated with its remaining performance from the cost-to-cost model in the fourth quarter of 2020. This resulted in the Company recognizing the remaining deferred revenue of \$15,145 to collaboration revenue in the year ended December 31, 2020. For the twelve months ended December 31, 2020, the Company recognized collaboration revenue of \$17,161.

All costs associated with the Research 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 twelve months ended December 31, 2020 and 2019:

	Balance as of December 31, 2019	Additions	Deductions	Balance as of December 31, 2020
Year ended December 31, 2020				
Contract liabilities:				
Deferred revenue - related party	\$ 110,071	10,000	(11,897)	\$ 108,174
Deferred revenue	\$ 9,668	7,493	(17,161)	\$ -
Year ended December 31, 2019				
Contract liabilities:				
Deferred revenue - related party	\$ 137,259	—	(27,188)	\$ 110,071
Deferred revenue	\$ -	15,883	(6,215)	\$ 9,668

During the twelve months ended December 31, 2020 the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods:

	Year Ended December 31,	
	2020	2019
Revenue recognized in the period from:		
Amounts included in the contract liability at the beginning of the period	\$ 21,565	\$ 27,188

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.

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

13. Net Loss per Share

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

	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net loss attributable to common stockholders	\$ (89,127)	\$ (70,279)	\$ (98,942)
Denominator:			
Weighted average common shares outstanding, basic and diluted	79,789,220	56,649,220	40,743,492
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.12)	\$ (1.24)	\$ (2.43)

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. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2020	2019	2018
Stock options to purchase common stock	10,037,130	8,310,683	7,561,719
Unvested restricted stock units	6,500	130,000	226,900
Shares issuable under employee stock purchase plan	10,786	89,821	49,495
	<u>10,054,416</u>	<u>8,530,504</u>	<u>7,838,114</u>

14. Commitments and Contingencies

Leases

Refer to Note 7 "Leases" for discussion of the commitments associated with the Company's lease portfolio.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third-parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2020 or 2019.

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.

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

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, 2020 and December 31, 2019.

15. Income Taxes

During the years ended December 31, 2020, 2019 and 2018, 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,		
	2020	2019	2018
Federal statutory income tax rate	(21.0)%	(21.0)%	(21.0)%
Research and development tax credits	(6.4)	(5.8)	(7.2)
State taxes, net of federal benefit	(7.8)	(6.8)	(7.2)
Stock-based compensation	(5.8)	(1.7)	2.0
Other	0.2	(0.7)	0.8
Change in deferred tax asset valuation allowance	40.8	36.0	32.6
Effective income tax rate	—%	—%	—%

Net deferred tax assets as of December 31, 2020 and 2019 consisted of the following:

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 106,351	\$ 72,752
Research and development tax credit carryforwards	42,311	36,602
Capitalized organization costs	214	244
Stock-based compensation expense	11,615	12,783
Lease Liability	4,283	5,500
Charitable Contributions	15	13
Deferred Revenue	29,553	32,713
Accrued expenses	1,783	1,251
Capitalized research and development expenses	51	58
Section 163(j) limitation	540	-
Total deferred tax assets	\$ 196,716	\$ 161,916
Deferred tax liabilities:		
Depreciation and amortization	(510)	(1,467)
Right of use assets	(2,470)	(3,103)
Total deferred tax liabilities	(2,980)	(4,570)
Valuation allowance	\$ (193,736)	\$ (157,346)
Net deferred tax assets	\$ —	\$ —

As of December 31, 2020, the Company had net operating loss carryforwards ("NOLs") for federal and state income tax purposes of \$390,000 and \$386,900, respectively. Federal NOLs of \$119,781, generated before 2018, will begin expiring in varying amounts in 2035 unless utilized. The remaining federal NOLs of \$270,219, generated after 2017, will be carried forward indefinitely and could be used to offset up to 100% of taxable income of each future tax year for tax years before January 1, 2021 and up to 80% of taxable income in all other future tax years. Massachusetts does not follow federal time periods for NOLs and as such the Company's Massachusetts NOLs of \$386,900 will expire at various times starting in 2035. As of December 31, 2020, the Company

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

also had available research and development tax credit carryforwards for federal and state income tax purposes of \$36,400 and \$7,500, respectively, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of \$20,700. Utilization of the NOLs and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control or could result in a change of control in the future upon subsequent disposition. The Company conducted an analysis to determine if historical changes in ownership through August 31, 2015 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 August 31, 2015 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 the deferred tax assets as of December 31, 2020 and 2019. 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, 2020, 2019 and 2018 related primarily to the increases in NOLs, research and development tax credit carryforwards, stock-based compensation and decrease of the deferred rate due to tax reform were as follows:

	<u>Year Ended December 31,</u>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
Valuation allowance at beginning of year	\$ (157,346)	\$ (132,009)	\$ (94,126)
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	(36,390)	(25,337)	(37,883)
Valuation allowance as of end of year	<u>\$ (193,736)</u>	<u>\$ (157,346)</u>	<u>\$ (132,009)</u>

The Company had no unrecognized tax benefits or related interest and penalties accrued for the years ended December 31, 2020 and 2019. The Company will recognize 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 is currently under examination by the Internal Revenue Service ("IRS") for the period ended December 31, 2018 related to its R&D tax credits. 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.

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

16. Related Party Transactions

As described in Note 12, in January 2016 the Company entered into the License Agreement and, in November 2018, a letter agreement with Nestlé, successor in interest to Nestec, Ltd., for the development and commercialization of certain product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn's disease. Nestlé is a related party since Nestlé is one of the Company's significant stockholders and is related to Nestlé Health Science U.S. Holdings, Inc, another significant stockholder. During the years ended December 31, 2020, 2019, and 2018, the Company recognized \$11,897, \$27,188, and \$26,917, respectively, of related party revenue associated with the License Agreement. As of December 31, 2020 and 2019, there was \$108,174 and \$110,071, respectively, of deferred revenue related to the License Agreement, which is classified as current or non-current in the consolidated balance sheets. The Company has made no payments to Nestlé during the year ended December 31, 2020. There is no amount due from Nestlé as of December 31, 2020.

In July 2019, the Company entered into a sublease agreement with Flagship Pioneering, one of the Company's significant stockholders, to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in July 2019 and ends on the last day of the 24th calendar month following commencement, with no option to extend (see Note 7). Under this agreement, the Company recorded other income of \$1,813 and \$890 during the twelve months ended December 31, 2020 and 2019. The Company received cash payments of \$1,813 and \$890 during the twelve months ended December 31, 2020 and 2019.

17. 401(k) Savings Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Effective January 1, 2016, the Company elected to match 50% of the first 6% of an employee's deferral. Company contributions are expensed in the year for which they are declared. During the years ended December 31, 2020, 2019, and 2018 the Company recorded expense of \$586, \$542, and \$604, respectively, for 401(k) match contributions.

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 and amended and restated bylaws are summaries and are qualified in their entirety by reference to the applicable provisions of our restated certificate of incorporation and amended and restated bylaws, which have been publicly filed with the Securities and Exchange Commission. We encourage you to read our restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the General Corporation Law of the State of Delaware for more information.

Our authorized capital stock consists of:

- 200,000,000 shares of common stock, par value \$0.001 per share; and
- 10,000,000 shares of preferred stock, par value \$0.001 per share.

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 restated certificate of incorporation and amended restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation. 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 restated 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 restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interest, including transactions which provide for payment of a premium over the market price for our shares.

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

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

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

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

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

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

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

Stockholders Not Entitled to Cumulative Voting. Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors

standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

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

Choice of Forum. Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our restated certificate of incorporation or amended and restated 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 restated certificate of incorporation or bylaws to be inapplicable or unenforceable if challenged in a proceeding or otherwise.

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

The provisions of Delaware law, our restated certificate of incorporation and our 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.

SERES THERAPEUTICS, INC.

2015 INCENTIVE AWARD PLAN

I. PURPOSE

The Plan's purpose is to enhance the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing these individuals with equity ownership opportunities. Capitalized terms used in the Plan are defined in Section XI.

II. ELIGIBILITY

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

III. ADMINISTRATION AND DELEGATION

(a) Administration. The Plan is administered by the Administrator. The Administrator has authority to determine which Service Providers receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions and reconcile inconsistencies in the Plan or any Award as it deems necessary or appropriate to administer the Plan and any Awards. The Administrator's determinations under the Plan are in its sole discretion and will be final and binding on all persons having or claiming any interest in the Plan or any Award.

(b) Appointment of Committees. To the extent Applicable Laws permit, the Board may delegate any or all of its powers under the Plan to one or more Committees. The Board may abolish any Committee or re-vest in itself any previously delegated authority at any time.

IV. STOCK AVAILABLE FOR AWARDS

(a) Number of Shares. Subject to adjustment under Section VIII and the terms of this Section IV, Awards may be made under the Plan covering up to the Overall Share Limit. As of the Plan's effective date under Section X(c), the Company will cease granting awards under the Prior Plans; however, Prior Plan Awards will remain subject to the terms of the applicable Prior Plan. Shares issued under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares.

(b) Share Recycling. If all or any part of an Award or Prior Plan Award expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the Award or Prior Plan Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring) paid by the Participant for such Shares or not issuing any Shares covered by the Award or Prior Plan Award, the unused Shares covered by the Award or Prior Plan Award will, as applicable, become or again be available for Award grants under the Plan. Further, Shares delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award or Prior Plan Award and/or to satisfy any applicable tax withholding obligation (including Shares retained by the Company from the Award or Prior Plan Award being exercised or purchased and/or creating the tax obligation) will, as applicable, become or again be available for Award grants under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards or Prior Plan Awards shall not count against the Overall Share Limit.

(c) Incentive Stock Option Limitations. Notwithstanding anything to the contrary herein, no more than 17,200,000 Shares may be issued pursuant to the exercise of Incentive Stock Options.

(d) Substitute Awards. In connection with an entity's merger or consolidation with the Company or the Company's acquisition of an entity's property or stock, the Administrator may grant Awards in substitution for any options or other stock or stock-based awards granted before such merger or consolidation by such entity or its affiliate. Substitute Awards may be granted on such terms as the Administrator deems appropriate, notwithstanding

limitations on Awards in the Plan. Substitute Awards will not count against the Overall Share Limit, except that Shares acquired by exercise of substitute Incentive Stock Options will count against the maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options under the Plan.

(e) Non-Employee Director Compensation. Notwithstanding any provision to the contrary in the Plan, the Administrator may establish compensation for non-employee Directors from time to time, subject to the limitations in the Plan. The Administrator will from time to time determine the terms, conditions and amounts of all such non-employee Director compensation in its discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation, or other compensation, and the value (determined as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of Awards granted to a non-employee Director as compensation for services as a non-employee Director during any fiscal year of the Company may not exceed \$700,000. The Administrator may make exceptions to this limit for individual non-employee Directors in extraordinary circumstances, as the Administrator may determine in its discretion, provided that the non-employee Director receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee Directors.

V. STOCK OPTIONS AND STOCK APPRECIATION RIGHTS

(a) General. The Administrator may grant Options or Stock Appreciation Rights to Service Providers subject to the limitations in the Plan, including Section IX(i) with respect to Incentive Stock Options. The Administrator will determine the number of Shares covered by each Option and Stock Appreciation Right, the exercise price of each Option and Stock Appreciation Right and the conditions and limitations applicable to the exercise of each Option and Stock Appreciation Right. A Stock Appreciation Right will entitle the Participant (or other person entitled to exercise the Stock Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Stock Appreciation Right an amount determined by multiplying the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose and payable in cash, Shares valued at Fair Market Value or a combination of the two as the Administrator may determine or provide in the Award Agreement.

(b) Exercise Price. The Administrator will establish each Option's and Stock Appreciation Right's exercise price and specify the exercise price in the Award Agreement. The exercise price will not be less than 100% of the Fair Market Value on the grant date of the Option or Stock Appreciation Right.

(c) Duration of Options. Each Option or Stock Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that the term of an Option or Stock Appreciation Right will not exceed ten years.

(d) Exercise. Options and Stock Appreciation Rights may be exercised by delivering to the Company a written notice of exercise, in a form the Administrator approves (which may be electronic), signed by the person authorized to exercise the Option or Stock Appreciation Right, together with, as applicable, payment in full (i) as specified in Section V(e) for the number of Shares for which the Award is exercised and (ii) as specified in Section IX(e) for any applicable taxes. Unless the Administrator otherwise determines, an Option or Stock Appreciation Right may not be exercised for a fraction of a Share.

(e) Payment Upon Exercise. The exercise price of an Option must be paid in cash, wire transfer of immediately available funds or by check payable to the order of the Company or, subject to Section X(h), any Company insider trading policy (including blackout periods) and Applicable Laws, by:

(i) if there is a public market for Shares at the time of exercise, unless the Administrator otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price; provided that such amount is paid to the Company at such time as may be required by the Administrator;

(ii) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value;

(iii) to the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;

(iv) to the extent permitted by the Administrator, delivery of a promissory note or any other property that the Administrator determines is good and valuable consideration; or

(v) any combination of the above permitted payment forms (including cash, wire transfer or check).

VI. RESTRICTED STOCK; RESTRICTED STOCK UNITS

(a) General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the Company's right to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares) if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement. The Administrator will determine and set forth in the Award Agreement the terms and conditions for each Restricted Stock and Restricted Stock Unit Award, subject to the conditions and limitations contained in the Plan.

(b) Restricted Stock

(i) *Dividends*. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares, unless the Administrator provides otherwise in the Award Agreement. In addition, unless the Administrator provides otherwise, if any dividends or distributions are paid in Shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the Shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid.

(ii) *Stock Certificates*. The Company may require that the Participant deposit in escrow with the Company (or its designee) any stock certificates issued in respect of shares of Restricted Stock, together with a stock power endorsed in blank.

(c) Restricted Stock Units

(i) *Settlement*. The Administrator may provide that settlement of Restricted Stock Units will occur upon or as soon as reasonably practicable after the Restricted Stock Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, in a manner intended to comply with Section 409A.

(ii) *Stockholder Rights*. A Participant will have no rights of a stockholder with respect to Shares subject to any Restricted Stock Unit unless and until the Shares are delivered in settlement of the Restricted Stock Unit.

(iii) *Dividend Equivalents*. If the Administrator provides, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, settled in cash or Shares and subject to the same restrictions on transferability and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are granted and subject to other terms and conditions as set forth in the Award Agreement.

VII. OTHER STOCK OR CASH BASED AWARDS

Other Stock or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive Shares to be delivered in the future and including annual or other periodic or long-term cash bonus awards (whether based on specified Performance Criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Stock or Cash Based Awards will also be available as a payment form in the settlement of other Awards, as standalone payments and as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock or Cash Based Awards may be paid in Shares, cash or other property, as the

Administrator determines. Subject to the provisions of the Plan, the Administrator will determine the terms and conditions of each Other Stock or Cash Based Award, including any purchase price, performance goal (which may be based on the Performance Criteria), transfer restrictions, and vesting conditions, which will be set forth in the applicable Award Agreement.

VIII. ADJUSTMENTS FOR CHANGES IN COMMON STOCK AND CERTAIN OTHER EVENTS

(a) Equity Restructuring. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Section VIII, the Administrator will equitably adjust each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include adjusting the number and type of securities subject to each outstanding Award and/or the Award's exercise price or grant price (if applicable), granting new Awards to Participants, and making a cash payment to Participants. The adjustments provided under this Section VIII(a) will be nondiscretionary and final and binding on the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

(b) Corporate Transactions. In the event of any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:

(i) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(ii) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(iii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and/or applicable exercise or purchase price, in all cases, as determined by the Administrator;

(iv) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards and/or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Section IV hereof on the maximum number and kind of shares which may be issued) and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards;

(v) To replace such Award with other rights or property selected by the Administrator; and/or

(vi) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

(c) Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock, including any Equity Restructuring or any securities offering or other similar transaction, for administrative convenience, the Administrator may refuse to permit the exercise of any Award for up to sixty days before or after such transaction.

(d) General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section VIII(a) above or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares. The Administrator may treat Participants and Awards (or portions thereof) differently under this Section VIII.

IX. GENERAL PROVISIONS APPLICABLE TO AWARDS.

(a) Transferability. Except as the Administrator may determine or provide in an Award Agreement or otherwise for Awards other than Incentive Stock Options, Awards may not be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a domestic relations order, and, during the life of the Participant, will be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, will include references to a Participant's authorized transferee that the Administrator specifically approves.

(b) Documentation. Each Award will be evidenced in an Award Agreement, which may be written or electronic, as the Administrator determines. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Discretion. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

(d) Termination of Status. The Administrator will determine how the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status affects an Award and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.

(e) Withholding. Each Participant must pay the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with such

Participant's Awards by the date of the event creating the tax liability. The Company may deduct an amount sufficient to satisfy such tax obligations based on the minimum statutory withholding rates from any payment of any kind otherwise due to a Participant. Participants may satisfy such tax obligations in cash, by wire transfer of immediately available funds, by check made payable to the order of the Company, or subject to Section X(h) and any Company insider trading policy (including blackout periods), (i) to the extent permitted by the Administrator, in whole or in part by delivery of Shares, including Shares retained from the Award creating the tax obligation, valued at their Fair Market Value, (ii) if there is a public market for Shares at the time the tax obligations are satisfied, unless the Administrator otherwise determines, (A) delivery (including telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver

promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator, or (iii) any combination of the foregoing permitted payment forms (including cash, wire transfer or check). If any tax withholding obligation will be satisfied under clause (i) of the immediately preceding sentence by the Company's retention of Shares from the Award creating the tax obligation and there is a public market for Shares at the time the tax obligation is satisfied, the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the applicable Participant's behalf some or all of the Shares retained and to remit the proceeds of the sale to the Company or its designee, and each Participant's acceptance of an Award under the Plan will constitute the Participant's authorization to the Company and instruction and authorization to such brokerage firm to complete the transactions described in this sentence.

(f) Amendment of Award; Repricing. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type, changing the exercise or settlement date, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action will be required unless (i) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Section VIII or pursuant to Section X(f). Notwithstanding the foregoing or anything in the Plan to the contrary, the Administrator may, without the approval of the stockholders of the Company, reduce the exercise price per share of outstanding Options or Stock Appreciation Rights or cancel outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Stock Appreciation Rights.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (i) all Award conditions have been met or removed to the Company's satisfaction, (ii) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including any applicable securities laws and stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy any Applicable Laws. The Company's inability to obtain authority from any regulatory body having jurisdiction, which the Administrator determines is necessary to the lawful issuance and sale of any securities, will relieve the Company of any liability for failing to issue or sell such Shares as to which such requisite authority has not been obtained.

(h) Acceleration. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

(i) Additional Terms of Incentive Stock Options. The Administrator may grant Incentive Stock Options only to employees of the Company, any of its present or future parent or subsidiary corporations, as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. If an Incentive Stock Option is granted to a Greater Than 10% Stockholder, the exercise price will not be less than 110% of the Fair Market Value on the Option's grant date, and the term of the Option will not exceed five years. All Incentive Stock Options will be subject to and construed consistently with Section 422 of the Code. By accepting an Incentive Stock Option, the Participant agrees to give prompt notice to the Company of dispositions or other transfers (other than in connection with a Change in Control) of Shares acquired under the Option made within (i) two years from the grant date of the Option or (ii) one year after the transfer of such Shares to the Participant, specifying the date of the disposition or other transfer and the amount the Participant realized, in cash, other property, assumption of indebtedness or other consideration, in such disposition or other transfer. Neither the Company nor the Administrator will be liable to a Participant, or any other party, if an Incentive Stock Option fails or ceases to qualify as an "incentive stock option" under Section 422 of the Code. Any Incentive Stock Option or portion thereof that fails to qualify as an "incentive stock option" under Section 422 of the Code for any reason, including becoming exercisable with respect to Shares having a fair market value exceeding the \$100,000 limitation under Treasury Regulation Section 1.422-4, will be a Non-Qualified Stock Option.

X. MISCELLANEOUS.

(a) No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement.

(b) No Rights as Stockholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a stockholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Laws require, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award and instead such Shares may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on stock certificates issued under the Plan that the Administrator deems necessary or appropriate to comply with Applicable Laws.

(c) Effective Date and Term of Plan. The Plan will become effective on the day prior to the Public Trading Date and will remain in effect until the tenth anniversary of such date, unless earlier terminated by the Board. No Awards may be granted under the Plan during any suspension period or after Plan termination. Notwithstanding anything in the Plan to the contrary, an Incentive Stock Option may not be granted under the Plan after ten years from the earlier of (i) the date the Board adopted the Plan or (ii) the date the Company's stockholders approved the Plan, but Awards previously granted may extend beyond that date in accordance with the Plan. If the Plan is not approved by the Company's stockholders, (i) it will not become effective, (ii) no Awards shall be granted thereunder, and (iii) the Prior Plans will continue in full force and effect in accordance with their terms.

(d) Amendment of Plan. The Administrator may amend, suspend or terminate the Plan at any time; provided that no amendment, other than an increase to the Overall Share Limit, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as in effect before such suspension or termination. The Board will obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

(e) Provisions for Foreign Participants. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

(f) Section 409A.

(i) *General*. The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (A) exempt this Plan or any Award from Section 409A, or (B) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section X(f) or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A.

(ii) *Separation from Service*. If an Award constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award upon a termination of a Participant's Service Provider relationship will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or after the termination of the Participant's Service Provider relationship. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms means a "separation from service."

(iii) Payments to Specified Employees. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of “nonqualified deferred compensation” required to be made under an Award to a “specified employee” (as defined under Section 409A and as the Administrator determines) due to his or her “separation from service” will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such “separation from service” (or, if earlier, until the specified employee’s death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of “nonqualified deferred compensation” under such Award payable more than six months following the Participant’s “separation from service” will be paid at the time or times the payments are otherwise scheduled to be made.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company or any Subsidiary will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer, other employee or agent of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan’s administration or interpretation, against any cost or expense (including attorneys’ fees) or liability (including any sum paid in settlement of a claim with the Administrator’s approval) arising from any act or omission concerning this Plan unless arising from such person’s own fraud or bad faith.

(h) Lock-Up Period. The Company may, at the request of any underwriter representative or otherwise, in connection with registering the offering of any Company securities under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any Shares or other Company securities during a period of up to one hundred eighty days following the effective date of a Company registration statement filed under the Securities Act, or such longer period as determined by the underwriter.

(i) Data Privacy. As a condition for receiving any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant’s participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant’s name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the “*Data*”). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant’s participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the Participant’s country, or elsewhere, and the Participant’s country may have different data privacy laws and protections than the recipients’ country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant’s participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant’s participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section X(i) in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant’s ability to participate in the Plan and, in the Administrator’s discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws the consents in this Section X(i). For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

(j) Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

(k) Governing Documents. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary) that the Administrator has approved, the Plan will govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan will not apply.

(l) Governing Law. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding any state's choice-of-law principles requiring the application of a jurisdiction's laws other than the State of Delaware.

(m) Claw-back Provisions. All Awards (including any proceeds, gains or other economic benefit the Participant actually or constructively receives upon receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to any Company claw-back policy, including any claw-back policy adopted to comply with Applicable Laws (including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder) as set forth in such claw-back policy or the Award Agreement.

(n) Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

(o) Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Laws. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in conformance with Applicable Laws. To the extent Applicable Laws permit, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Laws.

(p) Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except as expressly provided in writing in such other plan or an agreement thereunder.

(q) Broker-Assisted Sales. In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section IX(e): (a) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other Participants in the Plan in which all participants receive an average price; (c) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (e) the Company and its designees are under no obligation to arrange for such sale at any particular price; and (f) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

XI. DEFINITIONS

As used in the Plan, the following words and phrases will have the following meanings:

(a) "**Administrator**" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

(b) "**Applicable Laws**" means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted.

(c) "**Award**" means, individually or collectively, a grant under the Plan of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units or Other Stock or Cash Based Awards.

(d) “**Award Agreement**” means a written agreement evidencing an Award, which may be electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.

(e) “**Board**” means the Board of Directors of the Company.

(f) “**Change in Control**” means and includes each of the following:

(i) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (A) and (B) of subsection (iii) below) whereby any “person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a “person” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or

(ii) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (i) or (iii)) whose election by the Board or nomination for election by the Company’s stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(iii) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company’s assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(A) which results in the Company’s voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company’s assets or otherwise succeeds to the business of the Company (the Company or such person, the “**Successor Entity**”)) directly or indirectly, at least a majority of the combined voting power of the Successor Entity’s outstanding voting securities immediately after the transaction, and

(B) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (B) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or portion of any Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (i), (ii) or (iii) with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a “change in control event,” as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a “change in control event” as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

(g) “**Code**” means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.

(h) “**Committee**” means one or more committees or subcommittees of the Board, which may include one or more Company directors or executive officers, to the extent Applicable Laws permit. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a “non-employee director” within the meaning of Rule 16b-3; however, a Committee member’s failure to qualify as a “non-employee director” within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.

(i) “**Common Stock**” means the common stock of the Company.

(j) “**Company**” means Seres Therapeutics, Inc., a Delaware corporation, or any successor.

(k) “**Consultant**” means any person, including any adviser, engaged by the Company or its parent or Subsidiary to render services to such entity if the consultant or adviser: (i) renders *bona fide* services to the Company; (ii) renders services not in connection with the offer or sale of securities in a capital-raising transaction and does not directly or indirectly promote or maintain a market for the Company’s securities; and (iii) is a natural person.

(l) “**Designated Beneficiary**” means the beneficiary or beneficiaries the Participant designates, in a manner the Administrator determines, to receive amounts due or exercise the Participant’s rights if the Participant dies or becomes incapacitated. Without a Participant’s effective designation, “Designated Beneficiary” will mean the Participant’s estate.

(m) “**Director**” means a Board member.

(n) “**Disability**” means a permanent and total disability under Section 22(e)(3) of the Code, as amended.

(o) “**Dividend Equivalents**” means a right granted to a Participant under the Plan to receive the equivalent value (in cash or Shares) of dividends paid on Shares.

(p) “**Employee**” means any employee of the Company or its Subsidiaries.

(q) “**Equity Restructuring**” means a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Common Stock (or other Company securities) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

(r) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

(s) “**Fair Market Value**” means, as of any date, the value of Common Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; or (iii) without an established market for the Common Stock, the Administrator will determine the Fair Market Value in its discretion.

(t) “**Greater Than 10% Stockholder**” means an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary corporation, as defined in Section 424(e) and (f) of the Code, respectively.

- (u) “**Incentive Stock Option**” means an Option intended to qualify as an “incentive stock option” as defined in Section 422 of the Code.
- (v) “**Non-Qualified Stock Option**” means an Option not intended or not qualifying as an Incentive Stock Option.
- (w) “**Option**” means an option to purchase Shares.
- (x) “**Other Stock or Cash Based Awards**” means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property.
- (y) “**Overall Share Limit**” means the sum of (i) 2,200,000 Shares; (ii) any shares of Common Stock which are subject to Prior Plan Awards which become available for issuance under the Plan pursuant to Section IV(b) and (iii) an annual increase on the first day of each calendar year beginning January 1, 2016 and ending on and including January 1, 2025, equal to the lesser of (A) 4% of the aggregate number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of Shares as is determined by the Board.
- (z) “**Participant**” means a Service Provider who has been granted an Award.
- (aa) “**Performance Criteria**” mean the criteria (and adjustments) that the Administrator may select for an Award to establish performance goals for a performance period, which may include the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders’ equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease, peer group results, or market performance indicators or indices.
- (bb) “**Plan**” means this 2015 Incentive Award Plan.
- (cc) “**Prior Plans**” means, collectively, the Seres Health, Inc. 2012 Stock Incentive Plan and any prior equity incentive plans of the Company or its predecessor.
- (dd) “**Prior Plan Award**” means an award outstanding under the Prior Plans as of the Plan’s effective date in Section X(c).
- (ee) “**Public Trading Date**” means the first date upon which the Common Stock is listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system, or, if earlier, the date on which the Company becomes a “publicly held corporation” for purposes of Treasury Regulation Section 1.162-27(c)(1).
- (ff) “**Restricted Stock**” means Shares awarded to a Participant under Section VI subject to certain vesting conditions and other restrictions.
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(gg) “**Restricted Stock Unit**” means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date, subject to certain vesting conditions and other restrictions.

(hh) “**Rule 16b-3**” means Rule 16b-3 promulgated under the Exchange Act.

(ii) “**Section 409A**” means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.

(jj) “**Securities Act**” means the Securities Act of 1933, as amended.

(kk) “**Service Provider**” means an Employee, Consultant or Director.

(ll) “**Shares**” means shares of Common Stock.

(mm) “**Stock Appreciation Right**” means a stock appreciation right granted under Section V.

(nn) “**Subsidiary**” means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

(oo) “**Termination of Service**” means the date the Participant ceases to be a Service Provider.

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SERES HEALTH, INC.
2015 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Unit Grant Notice (the "**Grant Notice**") have the meanings given to them in the 2015 Incentive Award Plan (as amended from time to time, the "**Plan**") of Seres Health, Inc. (the "**Company**").

The Company hereby grants to the participant listed below ("**Participant**") the Restricted Stock Units described in this Grant Notice (the "**RSUs**"), subject to the terms and conditions of the Plan and the Restricted Stock Unit Agreement attached hereto as **Exhibit A** (the "**Agreement**"), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Number of RSUs:

Vesting Commencement Date:

Vesting Schedule: [To be specified in individual award agreements]

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES HEALTH, INC.

PARTICIPANT

By: _____

By: _____

Print Name: _____

Print Name: _____

Title: _____

RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

**ARTICLE I.
GENERAL**

1.1 Award of RSUs and Dividend Equivalents.

(a) The Company has granted the RSUs to Participant effective as of the grant date set forth in the Grant Notice (the “**Grant Date**”). Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the RSUs have vested.

(b) The Company hereby grants to Participant, with respect to each RSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable RSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a “**Dividend Equivalent Account**”) for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

1.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The RSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company’s general assets.

**ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT**

2.1 Vesting; Forfeiture. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant’s Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the RSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

2.2 Settlement.

(a) RSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company’s option as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than sixty (60) days after the RSU’s vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an RSU is paid in cash, the amount of cash paid with respect to the RSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

ARTICLE III. TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

ARTICLE IV. OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the RSUs, the Shares subject to the RSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the RSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Unit Grant Notice (the “**Grant Notice**”) have the meanings given to them in the 2015 Incentive Award Plan (as amended from time to time, the “**Plan**”) of Seres Therapeutics, Inc. (the “**Company**”).

The Company hereby grants to the participant listed below (“**Participant**”) the Restricted Stock Units described in this Grant Notice (the “**RSUs**”), subject to the terms and conditions of the Plan and the Restricted Stock Unit Agreement attached hereto as **Exhibit A** (the “**Agreement**”), both of which are incorporated into this Grant Notice by reference.

Participant:	%%FIRST_NAME%- %%%LAST_NAME%-%
Grant Date:	%%OPTION_DATE, 'MM/DD/YYYY'%-%
Number of RSUs:	%%TOTAL_SHARES_GRANTED, '999,999,999'%-%
Vesting Commencement Date:	%%VEST_BASE_DATE, 'MM/DD/YYYY'%-%
Vesting Schedule:	Subject to the terms of the Agreement, the RSUs will vest as to 25% of the RSUs, on the first 15th day of a calendar month that immediately follows the first anniversary of the Vesting Commencement Date and as to an additional 6.25% of the total number of RSUs, upon completion of each three consecutive months of the Participant’s service as a Service Provider thereafter, such that 100% of the RSUs will be fully vested on the fourth anniversary of the first 15th day of a calendar month that immediately follows the Vesting Commencement Date.

By Participant’s signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES THERAPEUTICS, INC.

PARTICIPANT

By: _____

Print Name: Eric D. Shaff

%%FIRST_NAME%- %%%LAST_NAME%-%

Title: President & Chief Executive Officer

RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE I.
GENERAL1.1 Award of RSUs and Dividend Equivalents.

(a) The Company has granted the RSUs to Participant effective as of the grant date set forth in the Grant Notice (the “**Grant Date**”). Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the RSUs have vested.

(b) The Company hereby grants to Participant, with respect to each RSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable RSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a “**Dividend Equivalent Account**”) for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

1.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

1.3 Unsecured Promise. The RSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company’s general assets.

ARTICLE II.
VESTING; FORFEITURE AND SETTLEMENT

2.1 Vesting; Forfeiture. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant’s Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the RSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

2.2 Settlement.

(a) RSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company’s option as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than sixty (60) days after the RSU’s vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an RSU is paid in cash, the amount of cash paid with respect to the RSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid

in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

Article III.
TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

(c) Mandatory Sell to Cover

(i) By accepting this Award, Participant understands and agrees that as a condition of the grant of the RSUs hereunder, Participant is required to, and hereby affirmatively elects to (the "Sell to Cover Election"), (1) sell that number of Shares determined in accordance with this Section 3.2(c) as may be necessary to satisfy all applicable withholding obligations with respect to any taxable event arising in connection with the RSUs and similarly sell such number of Shares as may be necessary to satisfy all applicable withholding obligations with respect to any other awards of restricted stock units granted to Participant under the Plan or any other equity incentive plans of the Company or its predecessor, and (2) to allow the transfer agent (together with any other party the Company determines necessary to execute the Sell to Cover Election, the "Agent") to remit the cash proceeds of such sale(s) to the Company. Furthermore, Participant directs the Company to make a cash payment equal to the required tax withholding from the cash proceeds of such sale(s) directly to the appropriate taxing authorities.

(ii) Participant hereby appoints the Agent as Participant's agent and authorizes the Agent to (1) sell on the open market at the then prevailing market price(s), on the Participant's behalf, as soon as practicable on or after the date the Shares are issued upon the vesting of the RSUs, that number (rounded up to the next whole number) of the Shares so issued necessary to generate proceeds to cover (x) any tax withholding obligations incurred with respect to such vesting or issuance and (y) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto and (2) apply any remaining funds to Participant's tax withholding obligations hereunder. Participant hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold pursuant to this Section 3.2(c)(ii). Participant understands that the Agent may effect sales as provided in this Section 3.2(c)(ii) in one or more sales and that the average price for executions resulting from bunched orders will be assigned to Participant's account. In addition, Participant acknowledges that it may not be possible to sell Shares as provided by this Section 3.2(c)(ii) due to (1) a legal or contractual restriction applicable to Participant or the Agent, (2) a market disruption, or (3) rules governing order execution priority on the national exchange where the Shares may be traded. Participant further agrees and acknowledges that in the event the sale of Shares would result in material adverse harm

to the Company, as determined by the Company in its sole discretion, the Company may instruct the Agent not to sell Shares as provided by this Section 3.2(c)(ii). In the event of the Agent's inability to sell Shares, the Participant will continue to be responsible for the timely payment to the Company and/or its affiliates of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld, including but not limited to those amounts specified in this Section 3.2(c)(ii). Participant acknowledges that regardless of any other term or condition of this Section 3.2(c), the Agent will not be liable to Participant for (1) special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or (2) any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control. Participant hereby agrees to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of this Section 3.2(c). The Agent is a third-party beneficiary of this Section 3.2(c). This Section 3.2(c) shall terminate not later than the date on which all tax withholding obligations arising in connection with the Award have been satisfied.

(iii) Participant has carefully reviewed this Section 3.2(c) and Participant hereby represents and warrants that on the date hereof he or she is not aware of any material, nonpublic information with respect to the Company or any securities of the Company, is not subject to any legal, regulatory or contractual restriction that would prevent the Agent from conducting sales, does not have, and will not attempt to exercise, authority, influence or control over any sales of Shares effected by the Agent pursuant to the Agreement, and is entering into the Agreement and this election to "sell to cover" in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 (regarding trading of the Company's securities on the basis of material nonpublic information) under the Exchange Act. It is Participant's intent that this election to "sell to cover" comply with the requirements of Rule 10b5-1(c) (1)(i)(B) under the Exchange Act and be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act.

ARTICLE IV. OTHER PROVISIONS

4.1 Adjustments. Participant acknowledges that the RSUs, the Shares subject to the RSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the RSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

**SERES HEALTH, INC.
2015 INCENTIVE AWARD PLAN**

RESTRICTED STOCK GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Grant Notice (the "**Grant Notice**") have the meanings given to them in the 2015 Incentive Award Plan (as amended from time to time, the "**Plan**") of Seres Health, Inc. (the "**Company**").

The Company has granted to the participant listed below ("**Participant**") the shares of Restricted Stock described in this Grant Notice (the "**Restricted Shares**"), subject to the terms and conditions of the Plan and the Restricted Stock Agreement attached as **Exhibit A** (the "**Agreement**"), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Number of Restricted Shares:

Vesting Commencement Date:

Vesting Schedule: [To be specified in individual award agreements]

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES HEALTH, INC.

PARTICIPANT

By: _____

By: _____

Print Name: _____

Print Name: _____

Title: _____

RESTRICTED STOCK AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

**ARTICLE I.
GENERAL**

1.1 Issuance of Restricted Shares. The Company will issue the Restricted Shares to the Participant effective as of the grant date set forth in the Grant Notice and will cause (a) a stock certificate or certificates representing the Restricted Shares to be registered in Participant's name or (b) the Restricted Shares to be held in book-entry form. If a stock certificate is issued, the certificate will be delivered to, and held in accordance with this Agreement by, the Company or its authorized representatives and will bear the restrictive legends required by this Agreement. If the Restricted Shares are held in book-entry form, then the book-entry will indicate that the Restricted Shares are subject to the restrictions of this Agreement.

1.2 Incorporation of Terms of Plan. The Restricted Shares are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

**ARTICLE II.
VESTING, FORFEITURE AND ESCROW**

2.1 Vesting. The Restricted Shares will become vested Shares (the "**Vested Shares**") according to the vesting schedule in the Grant Notice except that any fraction of a Share that would otherwise become a Vested Share will be accumulated and will become a Vested Share only when a whole Vested Share has accumulated.

2.2 Forfeiture. In the event of Participant's Termination of Service for any reason, Participant will immediately and automatically forfeit to the Company any Shares that are not Vested Shares (the "**Unvested Shares**") at the time of Participant's Termination of Service, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Upon forfeiture of Unvested Shares, the Company will become the legal and beneficial owner of the Unvested Shares and all related interests and Participant will have no further rights with respect to the Unvested Shares.

2.3 Escrow.

(a) Unvested Shares will be held by the Company or its authorized representatives until (i) they are forfeited, (ii) they become Vested Shares or (iii) this Agreement is no longer in effect. By accepting this Award, Participant appoints the Company and its authorized representatives as Participant's attorney(s)-in-fact to take all actions necessary to effect any transfer of forfeited Unvested Shares (and Retained Distributions (as defined below), if any, paid on such forfeited Unvested Shares) to the Company as may be required pursuant to the Plan or this Agreement and to execute such representations or other documents or assurances as the Company or such representatives deem necessary or advisable in connection with any such transfer. The Company, or its authorized representative, will not be liable for any good faith act or omission with respect to the holding in escrow or transfer of the Restricted Shares.

(b) All cash dividends and other distributions made or declared with respect to Unvested Shares ("**Retained Distributions**") will be held by the Company until the time (if ever) when the Unvested Shares to which such Retained Distributions relate become Vested Shares. The Company will establish a separate Retained Distribution bookkeeping account ("**Retained Distribution Account**") for each Unvested Share with respect to which Retained Distributions have been made or declared in cash and credit the Retained Distribution Account (without interest) on the date of payment with the amount of such cash made or declared with respect to the Unvested Share. Retained Distributions (including any Retained Distribution Account balance) will immediately and automatically be forfeited upon forfeiture of the Unvested Share with respect to which the Retained Distributions were paid or declared.

(c) As soon as reasonably practicable following the date on which an Unvested Share becomes a Vested Share, the Company will (i) cause the certificate (or a new certificate without the legend required by this Agreement, if Participant so requests) representing the Share to be delivered to Participant or, if the Share is held in book-entry form, cause the notations indicating the Share is subject to the restrictions of this Agreement to be removed and (ii) pay to Participant the Retained Distributions relating to the Share.

2.4 Rights as Stockholder. Except as otherwise provided in this Agreement or the Plan, upon issuance of the Restricted Shares by the Company, Participant will have all the rights of a stockholder with respect to the Restricted Shares, including the right to vote the Restricted Shares and to receive dividends or other distributions paid or made with respect to the Restricted Shares.

ARTICLE III. TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of the Restricted Shares and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 Section 83(b) Election. If Participant makes an election under Section 83(b) of the Code with respect to the Restricted Shares, Participant will deliver a copy of the election to the Company promptly after filing the election with the Internal Revenue Service.

3.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Restricted Shares as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise deliverable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Restricted Shares, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Restricted Shares. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the Restricted Shares or the subsequent sale of the Restricted Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure this Award to reduce or eliminate Participant's tax liability.

ARTICLE IV. RESTRICTIVE LEGENDS AND TRANSFERABILITY

4.1 Legends. Any certificate representing a Restricted Share will bear the following legend until the Restricted Share becomes a Vested Share:

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO FORFEITURE IN FAVOR OF THE COMPANY AND MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF A RESTRICTED STOCK AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

4.2 Transferability. The Restricted Shares and any Retained Distributions are subject to the restrictions on transfer in the Plan and may not be sold, assigned or transferred in any manner unless and until they become Vested Shares. Any attempted transfer or disposition of Unvested Shares or related Retained Distributions prior to the time the Unvested Shares become Vested Shares will be null and void. The Company will not be required to (a) transfer on its books any Restricted Share that has been sold or otherwise transferred in violation of this Agreement or (b) treat as owner of such Restricted Share or accord the right to vote or pay dividends to any purchaser or other transferee to

whom such Restricted Share has been so transferred. The Company may issue appropriate “stop transfer” instructions to its transfer agent, if any, or make appropriate notations to the same effect in its records.

ARTICLE V. OTHER PROVISIONS

5.1 Adjustments. Participant acknowledges that the Restricted Shares are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

5.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company’s Secretary at the Company’s principal office or the Secretary’s then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant’s last known mailing address, email address or facsimile number in the Company’s personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

5.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

5.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Restricted Shares will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

5.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

5.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

5.9 Limitation on Participant’s Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Award.

5.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

5.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

SERES HEALTH, INC.
2015 INCENTIVE AWARD PLAN

STOCK OPTION GRANT NOTICE

Capitalized terms not specifically defined in this Stock Option Grant Notice (the “Grant Notice”) have the meanings given to them in the 2015 Incentive Award Plan (as amended from time to time, the “Plan”) of Seres Health, Inc. (the “Company”).

The Company hereby grants to the participant listed below (“Participant”) the stock option described in this Grant Notice (the “Option”), subject to the terms and conditions of the Plan and the Stock Option Agreement attached hereto as Exhibit A (the “Agreement”), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Exercise Price per Share:

Shares Subject to the Option:

Final Expiration Date:

Vesting Commencement Date:

Vesting Schedule: [To be specified in individual award agreements]

Type of Option Incentive Stock Option Non-Qualified Stock Option

By Participant’s signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

SERES HEALTH, INC.

PARTICIPANT

By: _____

By: _____

Print Name: _____

Print Name: _____

Title: _____

STOCK OPTION AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

**ARTICLE I.
GENERAL**

1.1 Grant of Option. Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the Option effective as of the grant date set forth in the Grant Notice (the “*Grant Date*”).

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

**ARTICLE II.
PERIOD OF EXERCISABILITY**

2.1 Commencement of Exercisability. The Option will vest and become exercisable according to the vesting schedule in the Grant Notice (the “*Vesting Schedule*”) except that any fraction of a Share as to which the Option would be vested or exercisable will be accumulated and will vest and become exercisable only when a whole Share has accumulated. Notwithstanding anything in the Grant Notice, the Plan or this Agreement to the contrary, unless the Administrator otherwise determines, the Option will immediately expire and be forfeited as to any portion that is not vested and exercisable as of Participant’s Termination of Service for any reason.

2.2 Duration of Exercisability. The Vesting Schedule is cumulative. Any portion of the Option which vests and becomes exercisable will remain vested and exercisable until the Option expires. The Option will be forfeited immediately upon its expiration.

2.3 Expiration of Option. The Option may not be exercised to any extent by anyone after, and will expire on, the first of the following to occur:

- (a) The final expiration date in the Grant Notice;
- (b) Except as the Administrator may otherwise approve, the expiration of three (3) months from the date of Participant’s Termination of Service, unless Participant’s Termination of Service is for Cause or by reason of Participant’s death or Disability;
- (c) Except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant’s Termination of Service by reason of Participant’s death or Disability; and
- (d) Except as the Administrator may otherwise approve, Participant’s Termination of Service for Cause.

As used in this Agreement, “*Cause*” means (i) if Participant is a party to a written employment or consulting agreement with the Company or its Subsidiary in which the term “cause” is defined (a “*Relevant Agreement*”), “*Cause*” as defined in the Relevant Agreement, and (ii) if no Relevant Agreement exists, (A) the Administrator’s determination that Participant failed to substantially perform Participant’s duties (other than a failure resulting from Participant’s Disability); (B) the Administrator’s determination that Participant failed to carry out, or comply with any lawful and reasonable directive of the Board or Participant’s immediate supervisor; (C) Participant’s conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation for any felony or indictable offense or crime involving moral turpitude; (D) Participant’s unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its Subsidiaries or while performing Participant’s duties and responsibilities for the Company or any of its Subsidiaries; or (E) Participant’s commission of an act of fraud, embezzlement, misappropriation, misconduct, or breach of fiduciary duty against the Company or any of its Subsidiaries.

**ARTICLE III.
EXERCISE OF OPTION**

3.1 Person Eligible to Exercise. During Participant's lifetime, only Participant may exercise the Option. After Participant's death, any exercisable portion of the Option may, prior to the time the Option expires, be exercised by Participant's Designated Beneficiary as provided in the Plan.

3.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised, in whole or in part, according to the procedures in the Plan at any time prior to the time the Option or portion thereof expires, except that the Option may only be exercised for whole Shares.

3.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Option as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Option.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

**ARTICLE IV.
OTHER PROVISIONS**

4.1 Adjustments. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the person entitled to exercise the Option) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

4.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Option will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

4.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

4.12 Incentive Stock Options. If the Option is designated as an Incentive Stock Option:

(a) Participant acknowledges that to the extent the aggregate fair market value of shares (determined as of the time the option with respect to the shares is granted) with respect to which stock options intended to qualify as “incentive stock options” under Section 422 of the Code, including the Option, are exercisable for the first time by Participant during any calendar year exceeds \$100,000 or if for any other reason such stock options do not qualify or cease to qualify for treatment as “incentive stock options” under Section 422 of the Code, such stock options (including the Option) will be treated as non-qualified stock options. Participant further acknowledges that the rule set forth in the preceding sentence will be applied by taking the Option and other stock options into account in the order in which they were granted, as determined under Section 422(d) of the Code. Participant also acknowledges that if the Option is exercised more than three (3) months after Participant’s Termination of Service, other than by reason of death or disability, the Option will be taxed as a Non-Qualified Stock Option.

(b) Participant will give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under this Agreement if such disposition or other transfer is made (a) within two (2) years from the Grant Date or (b) within one (1) year after the transfer of such Shares to Participant. Such notice will specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

* * * * *

SERES THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(as amended effective June 12, 2020)

Non-employee members of the board of directors (the “**Board**”) of Seres Therapeutics, Inc. (the “**Company**”) shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this “**Program**”). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a “**Non-Employee Director**”) who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. No Non-Employee Director shall have any rights hereunder, except with respect to stock options granted pursuant to the Program. This Program shall become effective on the date of the effectiveness of the Company’s Registration Statement on Form S-1 relating to the initial public offering of common stock (the “**Effective Date**”).

I. CASH COMPENSATION

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of \$35,000 for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:

1. *Chairman of the Board or Lead Independent Director.* A Non-Employee Director serving as Chairman of the Board or Lead Independent Director shall receive an additional annual retainer of \$20,000 for such service.

2. *Audit Committee.* A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of \$7,500 for such service.

3. *Compensation Committee.* A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation Committee shall receive an additional annual retainer of \$5,000 for such service.

4. *Nominating and Corporate Governance Committee.* A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance

Committee shall receive an additional annual retainer of \$7,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$3,500 for such service.

C. Payment of Retainers. The annual retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2015 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "**Equity Plan**") and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan, including without limitation with respect to any stock dividend, stock split, reverse stock split or other similar event affecting the Company's common stock that is effected prior to the Effective Date.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 60,000 shares of the Company's common stock on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "**Initial Awards.**" No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted an option to purchase 30,000 shares of the Company's common stock on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "**Subsequent Awards.**" For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent

that they are otherwise entitled, will receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

D. Terms of Awards Granted to Non-Employee Directors

1. *Exercise Price.* The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of common stock on the date the option is granted.

2. *Vesting.* Each Initial Award shall vest and become exercisable in four substantially equal annual installments following the date of grant, such that the Initial Award shall be fully vested on the fourth anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. Each Subsequent Award shall vest and become exercisable on the earlier of the first anniversary of the date of grant or the day immediately prior to the date of the next annual meeting of the Company's stockholders occurring after the date of grant, in either case subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through each such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term.* The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

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AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this “Agreement”), dated as of January 29, 2021 (the “Effective Date”), is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the “Company”), and David Ege, Ph.D (“Executive”) (collectively referred to as the “Parties” or individually referred to as a “Party”).

RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement, which shall supersede and replace any prior employment arrangement, including, but not limited to, the Employment Agreement, dated as of October 13, 2020, by and between the Company and Executive, as amended (the “Prior Agreement”).
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective as of the Effective Date, the Company shall continue to employ Executive and Executive shall remain in the employ of the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Executive Vice President and Chief Technology Officer of the Company, initially reporting directly to the Chief Executive Officer of the Company (the “CEO”) with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to Executive by the CEO. Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees)

without the consent of the CEO, provided that Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case as amended from time to time, as set forth in writing, and as delivered or made available to Executive (each, a "Policy").

2. Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$375,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board," and (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Bonus. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company (including medical, dental and 401(k) plans), subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations,

by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

3. Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability.* If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause.* The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause.* The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company for Good Reason.* Executive may resign Executive's employment with the Company for Good Reason, as defined below.

(vi) *Resignation from the Company Without Good Reason.* Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to paragraph (a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least forty-five (45) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company in its sole discretion. The failure by the Company to set forth in the Notice of Termination any fact or circumstance which contributes

to a showing of Cause shall not waive any right of the Company hereunder or preclude the Company from asserting such fact or circumstance in enforcing the Company's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company for Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, then, except as otherwise provided by Section 4(c) and subject to Executive signing on or before the 21st day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to the product of (x) 1.0 times (y) the Annual Base Salary, payable in the form of salary continuation in regular installments over the 12-month period following the date of Executive's Separation from Service (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company's fiscal year prior to the fiscal

year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company's group healthcare plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earlier of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, in either case, within 60 days prior to or 12 months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive's Separation from Service, and not revoking, the Release, and Executive's continued compliance with Section 5, Executive shall receive the following:

(i) without duplication, the payments and benefits described in Section 4(b);

(ii) an amount in cash equal to the product of (x) 1.0 times (y) the Target Bonus, payable in a lump sum within thirty (30) days following the later of Executive's Separation from Service and the date of a Change in Control; and

(iii) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall

immediately become 100% vested (and if the Date of Termination precedes the Change in Control, all such unvested awards shall remain outstanding and eligible to vest in accordance with this Section 4(c)(iii) if a Change Control occurs within 60 days after the Date of Termination, provided that in no event will any such award remain outstanding beyond the final expiration date of the award set forth in the documents governing such award), with any other equity or equity-based awards (including awards that vest in whole or in part based on the attainment of performance-vesting conditions) being governed by the terms of the applicable award agreement.

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive's employment and the termination of the Term.

5. **Restrictive Covenants**. Prior to the effectiveness of this Agreement, Executive has executed and delivered to the Company an Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "Proprietary Information Agreement"). Executive acknowledges and agrees that Executive continues to be bound by the existing terms of the Proprietary Information Agreement, and nothing in this Agreement affects or modifies the terms of the Proprietary Information Agreement. Executive acknowledges that the provisions of the Proprietary Information Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Proprietary Information Agreement.

6. **Assignment and Successors**.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. **Certain Definitions**.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) Executive's refusal to (A) substantially perform Executive's duties with the Company (other than any such failure resulting from Executive's Disability) or (B) comply with, in any material respect, any of the Company's Policies;

(ii) the Board's determination that Executive refused in any material respect to carry out or comply with any lawful and reasonable directive of the Board;

- (iii) Executive's material breach of a material provision of this Agreement;
- (iv) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;
- (v) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or
- (vi) Executive's commission of an act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates;

provided, however, that Executive's termination will not be considered for Cause unless and until (a) the Company has provided Executive, within 60 days of the Company's knowledge of the occurrence of the facts and circumstances underlying the Cause event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Cause and (b) in the case of alleged Cause under clause (i), (ii) or (iii) of the foregoing definition and to the extent the applicable condition or event is reasonably capable of being cured, Executive shall have failed to cure such condition or event within 30 days after the receipt of such notice.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the version of the Seres Therapeutics, Inc. 2015 Incentive Award Plan in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii)-(vi), either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) Disability. "Disability" shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company's employees, "disability" as defined in such long-term disability plan for the purpose of determining a participant's eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, "Disability" shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, "Disability" shall mean Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be for "Good Reason" if Executive resigns within ninety days after any of the following events, unless Executive consents to the applicable event: (i) a material decrease in Executive's Annual Base Salary, (ii) a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or positions, including Executive ceasing to report directly to the chief executive officer of the Company's ultimate parent company following a Change in Control (or of the Company if there is no such parent entity), (iii) the Company's material breach of a material provision of this Agreement or another written agreement with Executive or (iv) the relocation of Executive's primary office to a location more than 50 miles from the Boston metropolitan area. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within 60 days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) provided the Company with an opportunity to cure the same within 30 days after the receipt of such notice; and (c) the Company shall have failed to cure such condition within such 30 day period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4(b) and Section 4(c) hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the “Independent Advisors”). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a “parachute payment” within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the “base amount” (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, the Chief Financial Officer at its headquarters,
- (ii) If to Executive, at the last address that the Company has in its personnel records for Executive, or
- (iii) at any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Proprietary Information Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties

to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including the Prior Agreement. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) No Inconsistent Actions. The Parties hereto shall not voluntarily undertake or fail to undertake any action or course of action inconsistent with the provisions or essential intent of this Agreement. Furthermore, it is the intent of the Parties hereto to act in a fair and reasonable manner with respect to the interpretation and application of the provisions of this Agreement.

(h) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(i) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney’s fees and expenses; provided that the arbitrator may assess the prevailing Party’s fees and costs against the non-prevailing Party as part of the arbitrator’s award.

The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided, however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or Proprietary Information Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association (“AAA”) shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

(j) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(k) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(l) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive’s termination of employment shall be payable only upon Executive’s “separation from service” with the Company within the meaning of Section 409A (a “Separation from Service”) and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive’s Separation from Service (the “First Payment Date”). Any installment payments that would have been made to Executive during the thirty (30) day period

immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

SERES THERAPEUTICS, INC.

By: /s/ Eric D. Shaff

Name: Eric D. Shaff

Title: President, CEO

/s/ David S. Ege

David Ege, Ph.D.

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between David Ege, Ph.D. ("Executive") and Seres Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Amended and Restated Employment Agreement, dated as of _____, 2021 (the "Employment Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section 4(b) and/or Section 4(c) of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their respective current and former officers, directors, equity holders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of Executive's or their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning,

or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standard Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including Executive's right to receive an award for information provided to any such government agencies), Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering monetary or other individual relief from the Company or any Releasee in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by Executive or by anyone else on Executive's behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties expressly agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Post-Termination Obligations. Executive reaffirms Executive's continuing obligations under the Proprietary Information Agreement between Executive and the Company

dated as of [_____], and, without limiting the foregoing, Executive makes the non-competition covenants set forth in the Proprietary Information Agreement as if set forth herein. In addition, Executive agrees to refrain from Disparaging (as defined below) the Company and its affiliates, including their respective services, technologies, practices, directors and officers. The Company agrees to instruct its officers and directors to refrain from Disparaging Executive. Nothing in this Section shall preclude any Party from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process, or to defend or enforce a Party's rights under this Agreement or the Employment Agreement. For purposes of this Agreement, "Disparaging" means making remarks, comments or statements, whether written or oral, that impugn the character, integrity, reputation or abilities of the individual or entity being disparaged.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c) and 9(i) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective upon the expiration of such seven business day period, so long as it has been signed by the Parties and has not been revoked by Executive before that date.

9. Trade Secrets; Whistleblower Protections. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement, the Employment Agreement, the Proprietary Information Agreement or any other agreement between Executive and the Company or any of its subsidiaries in effect as of the date Executive receives this Agreement (together, the "Subject Documents"): (a) Executive will not be in breach of the Subject Documents, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the Parties agree that nothing in the Subject Documents prohibits Executive from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal

law or regulation or releases or restrains Executive's right to receive an award for information provided to any such government agencies.

10. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated: _____

David Ege, Ph.D.

SERES THERAPEUTICS, INC.

Dated: _____

By: _____
Name:
Title:

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this “Agreement”), dated as of January 29, 2021 (the “Effective Date”), is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the “Company”), and Teresa L. Young (“Executive”) (collectively referred to as the “Parties” or individually referred to as a “Party”).

RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement, which shall supersede and replace any prior employment arrangement, including, but not limited to, the Employment Agreement, dated as of June 8, 2020, by and between the Company and Executive, as amended (the “Prior Agreement”).
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective as of the Effective Date, the Company shall continue to employ Executive and Executive shall remain in the employ of the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Executive Vice President and Chief Commercial and Strategy Officer of the Company, initially reporting directly to the Chief Executive Officer of the Company (the “CEO”) with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to Executive by the CEO. Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards

or committees) without the consent of the CEO, provided that Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case as amended from time to time, as set forth in writing, and as delivered or made available to Executive (each, a "Policy").

2. Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$360,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board," and (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Bonus. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company (including medical, dental and 401(k) plans), subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations,

by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

3. Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability.* If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause.* The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause.* The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company for Good Reason.* Executive may resign Executive's employment with the Company for Good Reason, as defined below.

(vi) *Resignation from the Company Without Good Reason.* Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to paragraph (a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least forty-five (45) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company in its sole discretion. The failure by the Company to set forth in the Notice of Termination any fact or circumstance which contributes

to a showing of Cause shall not waive any right of the Company hereunder or preclude the Company from asserting such fact or circumstance in enforcing the Company's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company for Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, then, except as otherwise provided by Section 4(c) and subject to Executive signing on or before the 21st day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to the product of (x) 1.0 times (y) the Annual Base Salary, payable in the form of salary continuation in regular installments over the 12-month period following the date of Executive's Separation from Service (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company's fiscal year prior to the fiscal

year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company's group healthcare plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earlier of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, in either case, within 60 days prior to or 12 months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive's Separation from Service, and not revoking, the Release, and Executive's continued compliance with Section 5, Executive shall receive the following:

(i) without duplication, the payments and benefits described in Section 4(b);

(ii) an amount in cash equal to the product of (x) 1.0 times (y) the Target Bonus, payable in a lump sum within thirty (30) days following the later of Executive's Separation from Service and the date of a Change in Control; and

(iii) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall

immediately become 100% vested (and if the Date of Termination precedes the Change in Control, all such unvested awards shall remain outstanding and eligible to vest in accordance with this Section 4(c)(iii) if a Change Control occurs within 60 days after the Date of Termination, provided that in no event will any such award remain outstanding beyond the final expiration date of the award set forth in the documents governing such award), with any other equity or equity-based awards (including awards that vest in whole or in part based on the attainment of performance-vesting conditions) being governed by the terms of the applicable award agreement.

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive's employment and the termination of the Term.

5. **Restrictive Covenants**. Prior to the effectiveness of this Agreement, Executive has executed and delivered to the Company an Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "Proprietary Information Agreement"). Executive acknowledges and agrees that Executive continues to be bound by the existing terms of the Proprietary Information Agreement, and nothing in this Agreement affects or modifies the terms of the Proprietary Information Agreement. Executive acknowledges that the provisions of the Proprietary Information Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Proprietary Information Agreement.

6. **Assignment and Successors**.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. **Certain Definitions**.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) Executive's refusal to (A) substantially perform Executive's duties with the Company (other than any such failure resulting from Executive's Disability) or (B) comply with, in any material respect, any of the Company's Policies;

(ii) the Board's determination that Executive refused in any material respect to

carry out or comply with any lawful and reasonable directive of the Board;

(iii) Executive's material breach of a material provision of this Agreement;

(iv) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(v) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(vi) Executive's commission of an act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates;

provided, however, that Executive's termination will not be considered for Cause unless and until (a) the Company has provided Executive, within 60 days of the Company's knowledge of the occurrence of the facts and circumstances underlying the Cause event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Cause and (b) in the case of alleged Cause under clause (i), (ii) or (iii) of the foregoing definition and to the extent the applicable condition or event is reasonably capable of being cured, Executive shall have failed to cure such condition or event within 30 days after the receipt of such notice.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the version of the Seres Therapeutics, Inc. 2015 Incentive Award Plan in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii)-(vi), either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) Disability. "Disability" shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company's employees, "disability" as defined in such long-term disability plan for the purpose of determining a participant's eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, "Disability" shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, "Disability" shall mean Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit

to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be for "Good Reason" if Executive resigns within ninety days after any of the following events, unless Executive consents to the applicable event: (i) a material decrease in Executive's Annual Base Salary, (ii) a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or positions, including Executive ceasing to report directly to the chief executive officer of the Company's ultimate parent company following a Change in Control (or of the Company if there is no such parent entity), (iii) the Company's material breach of a material provision of this Agreement or another written agreement with Executive or (iv) the relocation of Executive's primary office to a location more than 50 miles from the Boston metropolitan area. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within 60 days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) provided the Company with an opportunity to cure the same within 30 days after the receipt of such notice; and (c) the Company shall have failed to cure such condition within such 30 day period.

8. Parachute Payments

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4(b) and Section 4(c) hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section

409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the "Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, the Chief Financial Officer at its headquarters,
- (ii) If to Executive, at the last address that the Company has in its personnel records for Executive, or
- (iii) at any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Proprietary Information Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including the Prior Agreement. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) No Inconsistent Actions. The Parties hereto shall not voluntarily undertake or fail to undertake any action or course of action inconsistent with the provisions or essential intent of this Agreement. Furthermore, it is the intent of the Parties hereto to act in a fair and reasonable manner with respect to the interpretation and application of the provisions of this Agreement.

(h) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(i) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by

JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney's fees and expenses; provided that the arbitrator may assess the prevailing Party's fees and costs against the non-prevailing Party as part of the arbitrator's award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided, however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or Proprietary Information Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association ("AAA") shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

(j) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(k) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(l) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be

payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by

the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

SERES THERAPEUTICS, INC.

By: /s/ Eric D. Shaff
Name: Eric D. Shaff
Title: President, CEO

/s/ Teresa L. Young
Teresa L. Young

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Teresa L. Young ("Executive") and Seres Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Amended and Restated Employment Agreement, dated as of _____, 2021 (the "Employment Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section 4(b) and/or Section 4(c) of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their respective current and former officers, directors, equity holders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of Executive's or their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation,

or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standard Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including Executive's right to receive an award for information provided to any such government agencies), Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering monetary or other individual relief from the Company or any Releasee in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by Executive or by anyone else on Executive's behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties expressly agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Post-Termination Obligations. Executive reaffirms Executive's continuing obligations under the Proprietary Information Agreement between Executive and the Company

dated as of [_____], and, without limiting the foregoing, Executive remakes the non-competition covenants set forth in the Proprietary Information Agreement as if set forth herein. In addition, Executive agrees to refrain from Disparaging (as defined below) the Company and its affiliates, including their respective services, technologies, practices, directors and officers. The Company agrees to instruct its officers and directors to refrain from Disparaging Executive. Nothing in this Section shall preclude any Party from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process, or to defend or enforce a Party's rights under this Agreement or the Employment Agreement. For purposes of this Agreement, "Disparaging" means making remarks, comments or statements, whether written or oral, that impugn the character, integrity, reputation or abilities of the individual or entity being disparaged.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c) and 9(i) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective upon the expiration of such seven business day period, so long as it has been signed by the Parties and has not been revoked by Executive before that date.

9. Trade Secrets; Whistleblower Protections. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement, the Employment Agreement, the Proprietary Information Agreement or any other agreement between Executive and the Company or any of its subsidiaries in effect as of the date Executive receives this Agreement (together, the "Subject Documents"): (a) Executive will not be in breach of the Subject Documents, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the Parties agree that nothing in the Subject Documents prohibits Executive from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal

law or regulation or releases or restrains Executive's right to receive an award for information provided to any such government agencies.

10. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated: _____

Teresa L. Young

SERES THERAPEUTICS, INC.

Dated: _____

By: _____
Name:
Title:

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this “Agreement”), dated as of January 29, 2021 (the “Effective Date”), is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the “Company”), and Lisa von Moltke, M.D. (“Executive”) (collectively referred to as the “Parties” or individually referred to as a “Party”).

RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement, which shall supersede and replace any prior employment arrangement, including, but not limited to, the Employment Agreement, dated as of April 2, 2020, by and between the Company and Executive, as amended (the “Prior Agreement”).
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective as of the Effective Date, the Company shall continue to employ Executive and Executive shall remain in the employ of the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Executive Vice President and Chief Medical Officer of the Company, initially reporting directly to the Chief Executive Officer of the Company (the “CEO”) with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to Executive by the CEO. Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and

shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the CEO, provided that Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case as amended from time to time, as set forth in writing, and as delivered or made available to Executive (each, a "Policy").

2. **Compensation and Related Matters.**

(a) **Annual Base Salary.** During the Term, Executive shall receive a base salary at a rate of \$450,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board," and (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) **Bonus.** During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) **Benefits.** During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company (including medical, dental and 401(k) plans), subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) **Vacation.** During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) **Business Expenses.** During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) **Key Person Insurance.** At any time during the Term, the Company shall have the right to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably

cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

3. Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability.* If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause.* The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause.* The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company for Good Reason.* Executive may resign Executive's employment with the Company for Good Reason, as defined below.

(vi) *Resignation from the Company Without Good Reason.* Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to paragraph (a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least forty-five (45) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company in its sole discretion. The failure by

the Company to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause shall not waive any right of the Company hereunder or preclude the Company from asserting such fact or circumstance in enforcing the Company's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company for Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, then, except as otherwise provided by Section 4(c) and subject to Executive signing on or before the 21st day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to the product of (x) 1.0 times (y) the Annual Base Salary, payable in the form of salary continuation in regular installments over the 12-month period following the date of Executive's Separation from Service (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company's fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company's group healthcare plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earlier of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, in either case, within 60 days prior to or 12 months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive's Separation from Service, and not revoking, the Release, and Executive's continued compliance with Section 5, Executive shall receive the following:

(i) without duplication, the payments and benefits described in Section 4(b);

(ii) an amount in cash equal to the product of (x) 1.0 times (y) the Target Bonus, payable in a lump sum within thirty (30) days following the later of Executive's Separation from Service and the date of a Change in Control; and

(iii) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall immediately become 100% vested (and if the Date of Termination precedes the Change in Control, all such unvested awards shall remain outstanding and eligible to vest in accordance with this Section 4(c)(iii) if a Change Control occurs within 60 days after the Date of Termination, provided that in no event will any such award remain outstanding beyond the final expiration date of the award set forth in the documents governing such award), with any other equity or equity-based awards (including awards that vest in whole or in part based on the attainment of performance-vesting conditions) being governed by the terms of the applicable award agreement.

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive's employment and the termination of the Term.

5. **Restrictive Covenants**. Prior to the effectiveness of this Agreement, Executive has executed and delivered to the Company an Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement (the "Proprietary Information Agreement"). Executive acknowledges and agrees that Executive continues to be bound by the existing terms of the Proprietary Information Agreement, and nothing in this Agreement affects or modifies the terms of the Proprietary Information Agreement. Executive acknowledges that the provisions of the Proprietary Information Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Proprietary Information Agreement.

6. **Assignment and Successors**.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. **Certain Definitions**.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) Executive's refusal to (A) substantially perform Executive's duties with the Company (other than any such failure resulting from Executive's Disability) or (B) comply with, in any material respect, any of the Company's Policies;

- (ii) the Board's determination that Executive refused in any material respect to carry out or comply with any lawful and reasonable directive of the Board;
- (iii) Executive's material breach of a material provision of this Agreement;
- (iv) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;
- (v) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or
- (vi) Executive's commission of an act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates;

provided, however, that Executive's termination will not be considered for Cause unless and until (a) the Company has provided Executive, within 60 days of the Company's knowledge of the occurrence of the facts and circumstances underlying the Cause event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Cause and (b) in the case of alleged Cause under clause (i), (ii) or (iii) of the foregoing definition and to the extent the applicable condition or event is reasonably capable of being cured, Executive shall have failed to cure such condition or event within 30 days after the receipt of such notice.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the version of the Seres Therapeutics, Inc. 2015 Incentive Award Plan in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii)–(vi), either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) Disability. "Disability" shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company's employees, "disability" as defined in such long-term disability plan for the purpose of determining a participant's eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, "Disability" shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, "Disability" shall mean Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as

to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be for "Good Reason" if Executive resigns within ninety days after any of the following events, unless Executive consents to the applicable event: (i) a material decrease in Executive's Annual Base Salary, (ii) a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or positions, including Executive ceasing to report directly to the chief executive officer of the Company's ultimate parent company following a Change in Control (or of the Company if there is no such parent entity), (iii) the Company's material breach of a material provision of this Agreement or another written agreement with Executive or (iv) the relocation of Executive's primary office to a location more than 50 miles from the Boston metropolitan area. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within 60 days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with reasonable specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) provided the Company with an opportunity to cure the same within 30 days after the receipt of such notice; and (c) the Company shall have failed to cure such condition within such 30 day period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4(b) and Section 4(c) hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits

otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the “Independent Advisors”). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a “parachute payment” within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the “base amount” (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, the Chief Financial Officer at its headquarters,
- (ii) If to Executive, at the last address that the Company has in its personnel records for Executive, or
- (iii) at any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Proprietary Information Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including the Prior Agreement. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) No Inconsistent Actions. The Parties hereto shall not voluntarily undertake or fail to undertake any action or course of action inconsistent with the provisions or essential intent of this Agreement. Furthermore, it is the intent of the Parties hereto to act in a fair and reasonable manner with respect to the interpretation and application of the provisions of this Agreement.

(h) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(i) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by

JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney's fees and expenses; provided that the arbitrator may assess the prevailing Party's fees and costs against the non-prevailing Party as part of the arbitrator's award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided, however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or Proprietary Information Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association ("AAA") shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

(j) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(k) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(l) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be

payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by

the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

SERES THERAPEUTICS, INC.

By: /s/ Eric D. Shaff

Name: Eric D. Shaff

Title: President, CEO

/s/ Lisa von Moltke, M.D.

Lisa von Moltke, M.D.

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Lisa von Moltke, M.D. ("Executive") and Seres Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Amended and Restated Employment Agreement, dated as of _____, 2021 (the "Employment Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section 4(b) and/or Section 4(c) of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their respective current and former officers, directors, equity holders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of Executive's or their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning,

or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standard Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including Executive's right to receive an award for information provided to any such government agencies), Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering monetary or other individual relief from the Company or any Releasee in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by Executive or by anyone else on Executive's behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties expressly agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Post-Termination Obligations. Executive reaffirms Executive's continuing obligations under the Proprietary Information Agreement between Executive and the Company

dated as of [_____], and, without limiting the foregoing, Executive remakes the non-competition covenants set forth in the Proprietary Information Agreement as if set forth herein. In addition, Executive agrees to refrain from Disparaging (as defined below) the Company and its affiliates, including their respective services, technologies, practices, directors and officers. The Company agrees to instruct its officers and directors to refrain from Disparaging Executive. Nothing in this Section shall preclude any Party from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process, or to defend or enforce a Party's rights under this Agreement or the Employment Agreement. For purposes of this Agreement, "Disparaging" means making remarks, comments or statements, whether written or oral, that impugn the character, integrity, reputation or abilities of the individual or entity being disparaged.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c) and 9(i) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective upon the expiration of such seven business day period, so long as it has been signed by the Parties and has not been revoked by Executive before that date.

9. Trade Secrets; Whistleblower Protections. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement, the Employment Agreement, the Proprietary Information Agreement or any other agreement between Executive and the Company or any of its subsidiaries in effect as of the date Executive receives this Agreement (together, the "Subject Documents"): (a) Executive will not be in breach of the Subject Documents, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the Parties agree that nothing in the Subject Documents prohibits Executive from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal

law or regulation or releases or restrains Executive's right to receive an award for information provided to any such government agencies.

10. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated: _____

Lisa von Moltke, M.D.

Dated: _____

SERES THERAPEUTICS, INC.

By: _____

Name:

Title:

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-236824, 333-230092, 333-223514, 333-210171 and 333-205253) and Form S-3 (No.333-244401 and 333-237033) of Seres Therapeutics, Inc. of our report dated March 2, 2021 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 2, 2021

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 2, 2021

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

CERTIFICATIONS

I, Marcus Chapman, 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 2, 2021

By: /s/ Marcus Chapman
Marcus Chapman
Senior Vice President, Finance and Principal Financial and
Accounting Officer
(Principal Financial Officer)

**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, 2020 (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 2, 2021

/s/ Eric D. Shaff

Eric D. Shaff

President, Chief Executive Officer and Director
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marcus Chapman, Vice President, Finance and Principal Financial and Accounting 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, 2020 (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 2, 2021

/s/ Marcus Chapman

Marcus Chapman

Senior Vice President, Finance and Principal Financial and Accounting
Officer

(Principal Financial Officer)