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, 2025

OR

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

For the transition period from to

Commission File Number: 001-37465

Seres Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**27-4326290**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
101 Cambridgepark Drive Cambridge, Massachusetts	**02140**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 945-9626

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant based on the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on June 30, 2025, was $71,941,772. Solely for purposes of this disclosure, shares of common stock held by executive officers, directors and certain stockholders of the registrant as of such date have been excluded because such holders may be deemed to be affiliates.

As of March 6, 2026 there were 9,586,298 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 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025 are incorporated herein by reference in Part III.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including without limitation statements regarding our future results of operations and financial position including our projected cash runway, our requirement for additional funding, our business strategy, including potential strategic partnership efforts, our prospective products, the design, timing and results of our clinical studies and data readouts, product approvals, communications with, feedback from, or submissions to the FDA, research and development costs, the timing and likelihood of success, our ability to continue as a going concern, our ability to maintain compliance with any applicable Nasdaq listing requirements, executive and director transition matters, plans and objectives of management for future operations and future results of anticipated products, or the timing of any of the foregoing, 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 have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.
- We will need additional funding in order to advance development of our product candidates (including to conduct the Phase 2 study of SER-155 in allo-HSCT) and commercialize our product candidates, if approved. If we are unable to raise capital or secure a partnership or other business development transaction, we could be required to implement further cost-reduction measures, reduce or delay our product development programs or any potential future commercialization efforts, or pursue other alternatives, which could include seeking relief under the U.S Bankruptcy Code or winding down our operations.
- We are a clinical-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.

- The total amount of the Milestone Payments (as defined herein) we may receive from the Transaction is subject to various risks and uncertainties.
- We may not be able to realize the anticipated benefits of the Transaction (as defined herein), and we may face new challenges as a smaller, less diversified company.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are early in our development efforts of certain of our product candidates and may not be successful in our efforts to use our reverse translational platform to build a pipeline of product candidates and develop additional marketable drugs.
- Our product candidates are based on live biotherapeutics, which is a novel approach to therapeutic intervention.
- Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and any potential future 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.
- Disruptions at the FDA and other government agencies caused by funding shortages, government shutdowns, or staffing limitations 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.
- Current and future legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we may obtain.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or any collaborators will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired. Additionally, failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.
- 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.
- Even if any of our product candidates receive marketing approval, such product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We have in the past and may again in the future receive a notice of the failure to satisfy a continued listing rule from Nasdaq.

PART I

Item 1. Business

Overview

We are a clinical-stage company focused on improving patient outcomes in medically vulnerable populations through discovery and development of novel live biotherapeutic product, or LBP, candidates. We led the successful development and approval of VOWST, the first FDA-approved orally administered microbiome biotherapeutic and a Breakthrough Therapy designated drug, which was sold to Société des Produits Nestlé S.A., or SPN, and with certain of its affiliates, collectively, Nestlé Health Science, in September 2024. We have established field-leading capabilities and platforms that are powered by best-in-field human data sets to advance a portfolio of products that can uniquely address diseases by targeting host pathways that are modulated by microbes in the human body, and, in particular, diseases associated with mucosal barrier-immune interface targets. We believe clinical and nonclinical data across our programs support the development of LBPs to target the prevention and treatment of a broad swath of infections, and to treat inflammatory and immune, or I&I, diseases. Our pipeline consists of SER-155, SER-603, and SER-147, as well as other potential candidates in earlier development.

Our LBP candidates are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. We maintain a differentiated live biotherapeutics drug discovery and development platform that includes good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality. Our pipeline assets, including SER-155 and SER-603, are designed to target multiple disease-relevant pathways and are manufactured from standard clonal cell banks via cultivation. Our knowledge base and platforms enable selection of bacteria for precision consortia design to drive specific clinical outcomes and further provide unique insights on microbe-associated disease targets. We are designing LBP candidates to modulate host function to increase epithelium integrity and to induce immune homeostasis and tolerance, as well as to prevent the colonization and overgrowth of pathogens in the gastrointestinal, or GI, tract. We believe that the scientific and clinical data from the development of VOWST (our then product candidate SER-109 program) and the data from the SER-155 Phase 1b study (described below) validate our novel therapeutic approach in both infectious disease and I&I diseases. In the context of infection, we believe that our technology may be replicable across different bacterial pathogens with the potential to develop live biotherapeutics to protect a range of medically compromised patients at risk of antimicrobial resistance, or AMR, infections and bloodstream infections, or BSIs, that can result from a compromised epithelial barrier and that can be a major cause of mortality.

SER-155, our most advanced LBP candidate, is an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial BSIs, including those that can harbor antimicrobial resistance, as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HSCT. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT, and in December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. In our placebo-controlled Phase 1b study of SER-155 in allo-HSCT, SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post HSCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. Importantly, we observed clinical translation on the drug candidate's mechanisms of action, including improvements in epithelial integrity and immune homeostasis. Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HSCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with our CRO, and manufacturing of drug substance, we have paused additional investment in that program, preserving the optionality to efficiently restart the study, while continuing to seek funding for the Phase 2 study.

Our current strategy prioritizes advancing our programs that target I&I indications. We have meaningfully advanced over the past decade our scientific understanding of how microbes in the GI functionally modulate pathways at the mucosal barrier-immune interface that are associated with inflammatory and immune-related disease. The clinical data from our SER-155 Phase 1b study in allo-HSCT, along with our extensive preclinical and translational clinical data compiled over the past decade support and inform the advancement of our earlier stage programs targeting I&I diseases. We are evaluating SER-155 in immune checkpoint-related enterocolitis, or irEC, and we are developing SER-603, broadly in inflammatory bowel disease, or IBD, including ulcerative colitis, or UC, and Crohn's disease. We believe that our LBPs could represent a non-immunosuppressive treatment option for I&I diseases that are linked to colitis and could broadly address immune therapy toxicities, both of which represent significant unmet medical needs and potential commercial opportunities. We are currently exploring potential collaborations related to those I&I disease programs.

We have been collaborating with Memorial Sloan Kettering Cancer Center for over a decade on the impact of the GI microbiome on immune related diseases and cancer; recently this long-standing collaboration included an investigator-sponsored trial, or IST, evaluating SER-155 in 15 participants with irEC. irEC is among the most frequent and severe immune-related adverse events, or irAEs, in recipients of immune checkpoint inhibitor, or ICI, therapy and can be observed in up to 50% of patients, with rates varying based on cancer drug and treatment regimen. ICIs can cause a wide range of irAEs with links to T cell biology and epithelial barrier inflammation, both of which are biological functions shown in our preclinical and clinical pharmacology data to be positively impacted by SER-155. We expect to report initial clinical results, including preliminary safety, efficacy, pharmacology, and

exploratory biomarker data in the second quarter of 2026. We believe data from this IST could further support the potential for live biotherapeutics to address a significant unmet need among the large population of cancer patients receiving ICIs and may further support evaluation of our biotherapeutic approach in this setting.

SER-603 is a novel, LBP candidate optimized to address disruptions in the GI microbiome and to improve GI mucosal barrier integrity through the inhibition of inflammatory bacteria and associated metabolites, the promotion of epithelial barrier integrity to reduce the translocation of inflammatory molecules and barrier inflammation, and to induce immune homeostasis through non-immunosuppressive regulatory T cell, or T-reg, induction via T cell signaling. Our research on SER-603 has been primarily supported through a partnership with the Crohn's and Colitis Foundation, or CCF. These efforts aim to (i) confirm the functional phenotype and inflammatory state of patient subpopulations observed in our prior ulcerative colitis, or UC, clinical trials, and (ii) prioritize inflammatory targets and evaluate the potential to utilize biomarker-based patient selection and stratification for future studies. Many IBD patients experience an efficacy ceiling due to non-response or poor durability of response to existing therapies, and further, most advanced therapies target downstream inflammatory and immune responses and are immunosuppressive leading to toxicities and limitations with respect to combination therapies. IBD is a heterogeneous disease with both disruptions in the GI microbiome and epithelial barrier compromise being important drivers of disease that are not addressed by existing IBD therapies.

We believe that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations to address barrier compromise and bloodstream and AMR infections beyond allo-HSCT, including autologous-HSCT patients, cancer patients with neutropenia, chimeric antigen receptors therapy, or CAR-T, recipients, individuals with chronic liver disease, or CLD, solid organ transplant recipients, as well as patients in the intensive care unit, or ICU, and long-term acute care facilities. We continue to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including CLD. Additionally, we are developing an oral liquid formulation based on SER-155 strains, for dosing in patients who cannot take oral capsules, such as intubated patients in the ICU, and other medically vulnerable patients at high risk of AMR infections, supported by a grant from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator). We continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational development platform to prioritize future drug targets and to identify opportunities for monotherapy treatment and in combination with existing therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform and knowledge base, which we call our MbTx Platform, for the discovery and development of live biotherapeutics, and maintain extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for live biotherapeutics; and a strain library and associated microbiological capabilities that spans broad biological and functional breadth. This platform and knowledge base are integrated through a proprietary knowledge graph and agentic artificial intelligence, enabling rapid identification of specific microbes, microbial genes, and microbial metabolites/peptides associated with disease and the design of therapeutic consortia of bacteria for specific pharmacological properties to restructure the gut microbiome and modulate functional pathways associated with disease. In addition, we own a valuable intellectual property estate related to the development and manufacture of live biotherapeutics.

We have assembled a world class group of scientists, clinicians, directors and investors, who have established our leadership in the field of live biotherapeutics. We were founded by Flagship Pioneering, and our experienced management team possesses core capabilities and know-how in live biotherapeutics, drug development, regulatory approval, chemistry, manufacturing and controls, or CMC, commercialization, public company management and finance.

Our Strategy

Our goal is to remain the leading biopharmaceutical company developing live biotherapeutics to address significant unmet medical needs. We intend to advance our field-leading capabilities and platforms for the discovery and development of live biotherapeutics and leverage our translational platforms that are powered by best-in-field human data sets to advance a portfolio of early-stage products that can address diseases by targeting host pathways that are modulated directly by microbes or microbe produced metabolites and peptides in the human body, in particular diseases associated with mucosal barrier-immune interface targets. Having finalized the protocol for the Phase 2 study of SER-155 in patients undergoing allo-HSCT with the FDA and having advanced key study startup activities for this program, we will pause further investment while efforts to seek funding for the study remain ongoing. The SER-155 program has meaningfully advanced our understanding of how microbes in the GI tract functionally modulate pathways at the mucosal barrier-immune interface associated with inflammatory and immune-related diseases. Accordingly, our strategy moving forward will prioritize advancing our early-stage programs, including SER-603 that targets inflammatory and immune indications such as UC and Crohn's disease, and SER-155 in irEC, including supporting the read-out of clinical results from the fully enrolled investigator-sponsored SER-155 study in irEC which are expected in the second quarter of 2026.

Advancing our Programs

- ***Leverage scientific and clinical data from past successful drug development programs and apply learnings to advance early-stage pipeline programs in inflammatory and immune diseases (I&I)***. We believe clinical and nonclinical data across our programs support the development of live biotherapeutics to target the prevention and treatment of a broad range of I&I diseases such as UC, Crohn's disease, and irEC. We believe that the scientific and clinical data from the development of VOWST (our then product candidate SER-109 program) and the data from the SER-155 Phase 1b study validate our novel therapeutic approach. The SER-155 program has meaningfully advanced our understanding of how microbes in the GI tract functionally modulate pathways at the mucosal barrier-immune interface associated with I&I diseases. Discussions are ongoing with counterparties related to potential collaborations in these areas.
- ***Advance development of SER-155 in allo-HSCT.*** We intend to continue the development of SER-155, an investigational, oral, live biotherapeutic designed to decolonize GI pathogens and improve GI epithelial barrier integrity to prevent bacterial BSIs, including those that can harbor AMR, as well as other pathogen-associated negative clinical outcomes in patients undergoing allo-HSCT. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and graft versus host disease, or GvHD, in patients undergoing allo-HSCT. In September 2024, we announced topline clinical data from Cohort 2 of the SER-155 Phase 1b placebo-controlled study in patients undergoing allo-HSCT, in which SER-155 was associated with a significant reduction in BSIs (77% relative risk reduction), a significant reduction in systemic antibiotic exposure, and lower incidence of febrile neutropenia, in each case as compared to placebo, through day 100 post-HSCT. Additionally, SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. In December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. Seres has finalized the protocol for the Phase 2 study of SER-155 allo-HSCT patients with the FDA and has advanced key study startup activities. The planned Phase 2 study will incorporate a well-powered, placebo-controlled design, which provides for a planned interim analysis to enable an expedited initial data readout. Further investment in this program is paused while efforts to seek funding for the Phase 2 study remain ongoing.
- ***Maximize the broader opportunity of live biotherapeutics in other medically vulnerable patient populations in which there is a significant unmet need.*** We believe that SER-155 and SER-603 and other cultivated LBP candidates could be developed in additional patient populations to address mucosal barrier compromise and immune dysfunction associated disease as well as to address bloodstream and AMR infections beyond allo-HSCT, including autologous-HSCT patients, cancer patients with neutropenia, CAR-T, recipients, individuals with CLD, solid organ transplant recipients, as well as patients in the ICU and long-term acute care facilities. In July 2025, we were awarded a grant from CARB-X to support the development of an oral liquid formulation of SER-155 for medically vulnerable patient populations at risk of BSIs, including AMR infections, who cannot be dosed with oral capsules, such as intubated patients in the ICU. The CARB-X grant provides us with up to $3.6 million of funding for research, manufacture, and design of a Phase 1 clinical trial in ICU patients. We are also developing SER-147, an investigational live biotherapeutic designed to prevent bacterial bloodstream and SBP infections in patients with metabolic disease, including CLD. CLD is a progressive condition marked by deterioration of liver function and is reaching epidemic proportions affecting nearly 1.7 billion people worldwide, causing substantial health burden on afflicted countries. In the advanced stages of CLD, known as decompensated cirrhosis, patients exhibit significant immune dysfunction, microbiome disruption, and increased contact with the healthcare system, all of which drive increased susceptibility to bacterial infections.

Utilizing Our Capabilities

- ***Leverage our leading reverse translational platform to develop additional innovative and novel live biotherapeutics across a range of serious medical conditions with high unmet need including inflammatory disease, disease associated with modulation of host immunity, and infections.*** We believe that the combination of experience, proprietary data and proprietary know-how related to the microbiome, the functional properties of microbial species and strains, microbe-host interactions, the cultivation of microbial strains, and microbiome-specific functional screens and analytics provides us a competitive advantage in the design and development of live biotherapeutics. 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 live biotherapeutics.
- ***Develop manufacturing capabilities sufficient to support commercialization of any approved live biotherapeutic candidates.*** Live biotherapeutic 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 live biotherapeutic 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 live biotherapeutics.
- ***Leverage our regulatory success in a novel drug modality.*** Live biotherapeutics are a novel drug modality. Regulatory requirements for novel modalities can be complex and must ensure the safety and efficacy of the specific drug and also the manufacturing process, consistency, quality, and other potential effects of the platform. We successfully developed and

manufactured VOWST which obtained FDA Breakthrough Therapy and Orphan Drug Designations and obtained priority review approval of VOWST, the first FDA-approved orally administered microbiome therapeutic. This approval required substantial engagement with the FDA to develop relevant standards for live biotherapeutics and then achieve them for VOWST. Through the development of SER-155, we continue to have ongoing and constructive engagement with FDA. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT, and in December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. Additionally, we successfully developed a protocol for the SER-155 Phase 2 study, incorporating FD feedback. We believe these experiences provide capability and experience for the discovery, clinical development, manufacturing, and regulatory engagement supporting all of our other programs.

Our Live Biotherapeutics Platform

We have developed a field leading reverse translational biotherapeutics platform and knowledge base which we believe enables us to apply our capabilities to efficiently identify, manufacture and develop novel live biotherapeutics for serious human diseases. This platform 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* functional screening and disease models. To identify specific microbiome and host signatures that associate with disease or the onset of disease, we utilize data sets from healthy subjects and subjects with disease, or being treated for a disease, to delineate at high-resolution the microbial composition and functional profiles of the microbiome associated with the physiological state of subjects. These in-human insights on how different microbial strains, species, genes, metabolites or peptides directly or indirectly modulate disease-relevant functional pathways in the host are leveraged in preclinical drug design, optimization and development.

Our discovery process begins with human data derived from clinical trials and cohort studies, which we use as a data input for target identification and the design of our live biotherapeutic candidates. We compare healthy, normal colonic microbiomes to those in an unhealthy disrupted or disease state, revealing the ecological, compositional and functional differences between various states of disease and during the transition from health to disease or vice versa. Specifically, we utilize clinical data sets combined with advanced data sciences and customized, proprietary microbiome analytics to identify microbiome signatures of disease at the resolution of specific species and strains, metabolites, or genes that are associated with disease states. These microbiome biomarkers are associated with host signatures and biomarkers of disease to identify drug targets for our live biotherapeutics. Our clinical data from VOWST (developed as SER-109), SER-287, SER-301, SER-155, and other programs, and microbiome data generated with external collaborators, serve to instruct us on how the introduction of certain keystone microbes have the potential to restructure the microbiome and modulate the metabolic state of the gut to shift it to a non-disease state.

We have developed a proprietary, functionally characterized strain library and a suite of assays and screens, bioinformatics and computational tools, and databases, which facilitate our insights into the human microbiome. We have established proprietary, curated, reference databases and algorithms that: (i) integrate high-resolution genomic, metagenomic, metabolomic, and transcriptomic data sets, as well as data from *in vitro* and human cell-based functional screening 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 at the level of specific functional pathways. Our analytics leverage machine learning to 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 metabolites or functional pathways) that contribute to the state of disease or health. Additionally, leveraging all of these data we have curated and continue to maintain and expand a graphical database, or graphDB, that links and associates: (i) functional properties of microbial species/strains, (ii) functional pathways in hosts that can be modulated by the microbiome, (iii) the association of functional pathways to disease, and (iv) the association of existing non-microbiome drugs to the functional pathways. This continually growing graphDB is structured to be efficiently mined using machine learning and artificial intelligence algorithms to inform drug targets, drug design and optimization, and disease area and patient population prioritization. Further, this platform extends from preclinical design to clinical assessment of pharmacokinetics and pharmacodynamics of live biotherapeutics, enabling seamless translation from bench to bedside.

Our proprietary strain library of bacterial isolates from healthy donors and patients enables us to translate microbiome biomarker insights into defined consortia of bacteria. The strain library contains bacterial species isolated from individuals that are either healthy or that have a disease. We have developed extensive isolation and cultivation know-how. The strain library contains a majority of the Human Microbiome Project's "most wanted" species and many novel species we believe are not described in other databases nor found in other culture collections. 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 epithelial barrier cells in the gut and how they may modulate immune responses.

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

We manufacture the bacterial composition under current Good Manufacturing Practices, or cGMP, or similar foreign requirements, which are required by FDA and foreign regulators. We believe our unique manufacturing capacities, including our cultivation and quality systems, 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.

In addition, we believe our clinical development strategy represents a differentiated strategic advantage. Over more than a decade, we have established and maintained a broad and well-connected network of leading medical experts and principal investigators at academic medical centers, transplant centers, and other specialty clinical sites with deep expertise in microbiome science, immunology, infectious diseases, oncology, and gastrointestinal disorders. We believe this network, developed in part through our long-standing collaboration with Memorial Sloan Kettering Cancer Center, positions us to pursue a "light and fast" first-in-human and first-in-patient development paradigm. By leveraging investigator-sponsored studies, where appropriate, we can efficiently generate early clinical proof-of-mechanism and biomarker data in high priority and well-defined patient populations, refine dose strategies, and inform registrational development pathways while maintaining capital discipline. We believe this model enhances our ability to rapidly translate preclinical insights into human data, prioritize assets with the highest probability of success, and accelerate decision-making across our portfolio. Additionally, we have experience utilizing clinical trial strategies to advance the pipeline including but not limited to incorporation of adaptive designs, patient stratification, designing protocols with a patient-centric focus to reduce patient burden, use of historical comparator cohorts, and will consider other approaches including basket, umbrella and seamless designs as part of clinical development efforts.

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 LBP candidates represent a novel approach with potential application across a broad range of human diseases. We led the successful development and approval of VOWST, the first FDA-approved orally administered microbiome therapeutic and a Breakthrough Therapy designated drug, which was sold to Nestlé Health Science in September 2024. SER-155, our most advanced LBP candidate, is an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent BSIs, including those that can harbor AMR, as well as other pathogen-associated negative clinical outcomes in patients undergoing allo-HSCT. In our placebo-controlled Phase 1b study of SER-155 in allo-HSCT, Cohort 2 results demonstrated that SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post-HSCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. In December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. In January 2025, we reported exploratory translational biomarker data from the SER-155 Phase 1b study which provided evidence supporting the intended therapeutic mechanisms, including promotion of intestinal epithelial barrier integrity to reduce the potential of bacterial translocation into the bloodstream, and reduction of systemic inflammatory responses. Results from this exploratory biomarker analysis showed that SER-155 was associated with lower levels of fecal albumin and lower concentrations of various plasma biomarkers associated with systemic inflammation (i.e., IFN-y, TNF-α, IL-17, and IL-8) in the HSCT peri-transplant period, the period from the end of the first SER-155 treatment course through to neutrophil engraftment. The results support SER-155's intended mechanisms of action and reinforce the previously reported promising clinical study efficacy and safety data. These

systemic inflammatory response observations further support the potential to develop our live biotherapeutics to address inflammatory and immune diseases, including UC and Crohn's disease.

Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HSCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with our CRO, and manufacturing of drug substance, we have paused additional investment in that program, preserving the optionality to efficiently restart the study, while continuing to seek funding for the Phase 2 study.

Our current strategy prioritizes advancing our programs that target I&I indications. We have meaningfully advanced over the past decade our scientific understanding of how microbes in the GI functionally modulate pathways at the mucosal barrier-immune interface that are associated with inflammatory and immune-related disease. The clinical data from our SER-155 Phase 1b study in allo-HSCT, along with our extensive preclinical and translational clinical data compiled over the past decade support and inform the advancement of our earlier stage programs targeting I&I diseases. We are evaluating SER-155 in immune checkpoint-related enterocolitis, or irEC, and we are developing SER-603, broadly in inflammatory bowel disease, or IBD, including ulcerative colitis, or UC, and Crohn's disease. We believe that our LBPs could represent a non-immunosuppressive treatment option for I&I diseases that are linked to colitis and could broadly address immune therapy toxicities, both of which represent significant unmet medical needs and potential commercial opportunities. We are currently exploring potential collaborations related to those I&I disease programs.

We have been collaborating with Memorial Sloan Kettering Cancer Center for over a decade on the impact of the gastrointestinal microbiome on immune related diseases and cancer; recently this long-standing collaboration included an IST evaluating SER-155 in 15 participants with irEC. irEC is among the most frequent and severe irAEs in recipients of ICI therapy and can be observed in up to 50% of patients, with rates varying based on cancer drug and treatment regimen. ICIs can cause a wide range of irAEs with links to T cell biology and epithelial barrier inflammation, both of which are biological functions shown in our preclinical and clinical pharmacology data to be positively impacted by SER-155. We expect to report initial clinical results, including preliminary safety, efficacy, pharmacology, and exploratory biomarker data in the second quarter of 2026. We believe data from this IST could further support the potential for live biotherapeutics to address a significant unmet need among the large population of cancer patients receiving ICIs and may further support evaluation of our biotherapeutic approach in this setting.

SER-603 is a novel, LBP candidate optimized to address disruptions in the GI microbiome and to improve GI mucosal barrier integrity through the inhibition of inflammatory bacteria and associated metabolites, the promotion of epithelial barrier integrity to reduce the translocation of inflammatory molecules and barrier inflammation, and to induce immune homeostasis through non-immunosuppressive regulatory T cell, or T-reg, induction via T cell signaling. Our research on SER-603 has been primarily supported through a partnership with the Crohn's and Colitis Foundation, or CCF. These efforts aim to (i) confirm the functional phenotype and inflammatory state of patient subpopulations observed in our prior ulcerative colitis, or UC, clinical trials, and (ii) prioritize inflammatory targets and evaluate the potential to utilize biomarker-based patient selection and stratification for future studies. Many IBD patients experience an efficacy ceiling due to non-response or poor durability of response to existing therapies, and further, most advanced therapies target downstream inflammatory and immune responses and are immunosuppressive leading to toxicities and limitations with respect to combination therapies. IBD is a heterogeneous disease with both disruptions in the GI microbiome and epithelial barrier compromise being important drivers of disease that are not addressed by existing IBD therapies.

We believe that our cultivated live biotherapeutic candidates could be developed in additional patient populations to address barrier compromise and bloodstream and antimicrobial resistant infections, including autologous-HSCT patients, cancer patients with neutropenia, CAR-T, recipients, individuals with CLD, solid organ transplant recipients, as well as patients in the ICU and long-term acute care facilities. We continue to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and SBP, infections in patients with metabolic disease, including CLD. Additionally, we are developing an oral liquid formulation based on SER-155 strains, for dosing in patients who cannot take oral capsules, such as intubated patients in the ICU, and other medically vulnerable patients at high risk of antimicrobial resistant infections, supported by a grant from CARB-X. We continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational development platform to prioritize future drug targets and to identify opportunities for monotherapy treatment and in combination with existing therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

Immunology and Inflammation

Irritable Bowel Disease and Ulcerative Colitis

UC, a form of IBD, is a relapsing-remitting chronic inflammatory disorder affecting the mucosal surface of the colon, leading to episodes of bloody diarrhea, urgency and mucosal inflammation (Danese and Fiocchi, 2011), which generally begins in young adulthood and endures for life. The incidence of UC is rising worldwide, and the prevalence of the disease is highest in the United States, Canada, and Europe. In the United States alone, the prevalence of UC is estimated to be 378 per 100,000, or approximately 1.25 million Americans (Lewis et al., 2023). The severity, extent, and duration of disease are also risk factors for developing colon cancer, which occurs at a rate as high as 0.5-1.0% per year, an important complication given the young age at which the disease

strikes. Patients with UC also experience increased risk of *Clostridioides difficile* infection, or CDI, and primary sclerosing cholangitis, compared to the general population (Dlalal & Allegretti, 2022).

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

Current IBD therapies primarily suppress immune responses rather than address upstream drivers of immune activation. Despite advances in biologics and small molecules, many patients fail to achieve durable remission, and a substantial subset experience incomplete response, loss of response over time, or safety limitations associated with chronic immunosuppression. Additionally, current therapeutic approaches in IBD do not address the potential role of microbiome functional disruptions in causing or aggravating disease in IBD. However, not all patients with IBD present with microbiome disruption; many patients with IBD demonstrate comparable taxonomic and functional microbiome diversity to healthy subjects (Lloyd-Price 2019). Similarly, pre-clinical models have shown that microbiomes from patients with IBD drive variable immune responses, with only a subset of microbiomes resulting in inflammation (Hart et al. 2017; Britton et al. 2019). These data suggest that the microbiome may play a role in a subset of subjects with IBD.

Data from our SER-287 Phase 2b study and the first cohort of subjects from our SER-301 Phase 1b study in patients with mild-to-moderate UC suggest that the pharmacodynamic effects observed for SER-287 and SER-301 were greater in a subset of patients. Based on these results, we continue to advance research and development activities supported by partnerships to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts in IBD, and to further optimize our live biotherapeutic lead candidates. In October 2023, we were awarded a $500,000 grant from the CCF to leverage our clinical results and biological mechanism insights to functionally characterize subpopulations and to define associated biomarkers for IBD patient selection and stratification of patients where the GI microbiome plays an active role in inflammation and could be modified to reduce colitis. Our preclinical studies conducted to date have recapitulated the patient subpopulation observations from the previously run trials and progressed associated biomarker delineation of the populations, as well as confirmed a microbiome-driven functional link to disease. These research efforts aim to prioritize inflammatory targets for future clinical trials and evaluate the potential to utilize biomarker-based patient selection and stratification for these future studies.

SER-603

SER-603 is an investigational live biotherapeutic designed to improve response rates and durability of remission in patients with IBD, including UC and Crohn's disease. SER-603 is being developed for use as either a stand-alone therapy in mild-to-moderate disease or as a mechanism-distinct adjunctive therapy in combination with biologics or small molecules in moderate-to-severe disease. The program leverages our prior clinical experience in UC, including learnings from SER-287 and SER-301, and incorporates biomarker-driven patient stratification and optimized microbiome conditioning strategies.

SER-603 is in preclinical development, with IND-enabling activities ongoing. The program is supported by translational analyses from prior clinical studies and by preclinical studies that have recapitulated microbiome-defined patient subpopulation observations. We continue to evaluate biomarker-based patient selection approaches and functional characterization strategies to inform future clinical development.

Emerging clinical and preclinical evidence suggests that microbiome functional disruption contributes to disease activity in a defined subset of IBD patients. Observational and translational data from our prior SER-287 Phase 2b study and SER-301 Phase 1b study indicate that pharmacodynamic responses were greater in microbiome-defined subpopulations. These findings, along with external data demonstrating heterogeneity in microbiome-associated inflammatory responses, support the development of targeted, biomarker-informed live biotherapeutic strategies. We have discovered more than fifty GI bacterial features linked to inflammatory outcomes and have nominated and validated microbe associated biomarkers that can predict a response to current advanced therapies for IBD. Leveraging these biomarkers and our integrated preclinical and clinical data sets, SER-603 is optimized to address epithelial barrier dysfunction and microbiome-driven inflammation without systemic immunosuppression.

Given the chronic nature of IBD and continued unmet need for safe, durable, and non-immunosuppressive treatment options, we believe SER-603 has the potential to address a substantial commercial opportunity. SER-603 targets multiple segments of the IBD market, including moderate-to-severe UC (approximately 300,000-400,000 patients in the United States) as combination therapy with current standards of care, moderate-to-severe Crohn's disease in combination therapy setting, and mild-to-moderate UC and Crohn's disease as potential monotherapy.

Immune checkpoint-related enterocolitis (irEC)

IrEC is among the most frequent and severe irAEs in recipients of immune checkpoint-inhibitor therapy and can be observed in up to 50% of patients with rates varying based on cancer drug and treatment regimen. Immune checkpoint inhibitors can cause a wide range of irAEs with links to T cell biology and epithelial barrier inflammation, both of which are biological functions shown in

our preclinical and clinical pharmacology data to be positively impacted by SER-155. We believe that supportive data from this study could provide further support for the expansion of indications that may be well suited for our biotherapeutic approach.

Immune checkpoint inhibitors are a commonly used class of drugs that promote anti-tumor immune activity for cancer treatment. irEC represents a growing and underserved market driven by the rapid expansion of ICI use across oncology. Importantly, irEC shares substantial pathophysiologic overlap with inflammatory bowel disease (IBD), including epithelial barrier dysfunction, dysregulated mucosal immunity, and microbiome perturbation. This biological convergence enables clinical, regulatory, and commercial synergies between irEC and IBD development programs. With approximately 500,000 patients using ICI globally, approximately 50,000 to 100,000 are anticipated to experience clinically significant irEC. irEC rates vary, with rates highest in CTLA-4-based and combination therapies (~50%); grade 2+ irEC can lead to discontinuation of therapy, risking further cancer progression.

SER-155 in irEC

SER-155 is currently being evaluated as a first-in-class live biotherapeutic candidate for the treatment of Grade 2–3 immune checkpoint inhibitor-related enterocolitis (irEC) as a result of ICI therapy. The program is designed to promote mucosal healing and modulate inflammation without systemic immunosuppression, with the goal of reducing or eliminating the need for high-dose corticosteroids, which carry the risk of toxicity and ICI efficacy impact. We believe SER-155 could be a first-in-class therapy as current approaches manage toxicity reactively with immunosuppression, which can negatively impact cancer treatment.

We are nearing completion of a single-arm, open-label Phase 1b investigator-sponsored trial conducted with Memorial Sloan Kettering Cancer Center evaluating SER-155 as first-line treatment of irEC. The study was fully enrolled (n=15) in early 2026, and we expect to report initial clinical results, including preliminary safety, efficacy, pharmacology, and exploratory biomarker data in the second quarter of 2026.

Infection Risk Reduction

We continue to be invested in the infectious disease space, with a renewed focus on leveraging our existing clinical data, translational insights, and manufacturing capabilities to support targeted development efforts across a defined set of related indications. We believe that the scientific and clinical data from our VOWST program (our then product candidate SER-109 program) validate our novel approach of using live biotherapeutics to decolonize pathogens and improve epithelial barrier integrity, resulting in reduced rate of infections in medically compromised patients. Data from the ECOSPOR III and ECOSPOR IV Phase 3 trial published in the *New England Journal of Medicine* (Feuerstadt et al., 2022) and *Journal of the American Medical Association* (Sims et al., 2023) suggest that live biotherapeutics have the potential to restructure the gut microbiome and shift the gut metabolic landscape. Additional data show that VOWST rapidly reduced the abundance of bacteria associated with common antibiotic resistance genes, or ARGs, and reduced ARG abundance in the gut (Straub et al., 2023). Collectively, we believe these data suggest the potential for live biotherapeutics to prevent the colonization and overgrowth of pathogens that can establish in the gut and ultimately to reduce infections. We believe that reducing pathogen colonization in the GI and improving GI epithelial barrier integrity to reduce the risk of infection may be replicable in a range of medically compromised patients, protecting them from infections and resulting downstream clinical sequelae.

We believe this approach may also enable us to reduce AMR, which the World Health Organization declared as a top ten global public health threat facing humanity, and with estimates that yearly deaths may reach 10 million by 2050, putting mortality due to AMR on par with deaths due to cancer. Recently, two manuscripts were published in *Nature Medicine* (Bryant et al. 2026) and the *Journal of Infectious Diseases* (Bryant et al. 2025) highlighting new insights into the functional mechanism and clinical impact of VOWST. The *Nature Medicine article*, titled "The impact of an oral purified microbiome therapeutic on the GI microbiome", confirmed our pharmacological hypotheses from earlier VOWST studies, with higher VOWST dosing associated with enhanced pharmacokinetics, as assessed by faster and more robust therapeutic species engraftment in the gut. Treatment also significantly altered the composition of the intestinal microbiome and microbe-associated metabolites, including decreased primary and increased secondary bile acids, as well as elevated short- and medium-chain fatty acids, functional changes that inhibit C. difficile spore germination and vegetative growth. Further, in vitro analyses confirmed that VOWST batches induced production of these metabolites that disrupt C. difficile life cycle and growth. Collectively, these findings support VOWST's role in restoring microbe-associated metabolic functions critical to preventing CDI recurrence. A complementary publication in the *Journal of Infectious Diseases*, titled "Comparability of Gastrointestinal Microbiome and Bile Acid Profiles in Patients With First or Multiply Recurrent Clostridioides difficile Infection", reported a post hoc analysis of the ECOSPOR IV Phase 3 trial, evaluating differences in gastrointestinal microbiome and bile acid profiles between patients experiencing a first recurrence C. difficile infection (frCDI) versus multiply recurrence infection (mrCDI). These data demonstrate that the underlying functional disease etiology is consistent in both first and multiply recurrent CDI patient populations, with VOWST demonstrating similar efficacy and drug pharmacology across the broad patient population.

We believe these data provide important clinical translation and further demonstrate the potential of live biotherapeutics to target specific microbiome functions that are linked to serious disease, including those that are not effectively treated with other drug modalities. The underlying data supporting these publications was developed using Seres MbTx platform, which provides high-resolution assessment of drug pharmacology and functional mechanism of action. These data on bacterial function and pharmacology

anchored the preclinical development of SER-155 and inform the continued development of Seres' pipeline of next-generation live biotherapeutic products.

SER-155 in allo-HSCT

We are developing SER-155, an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial BSIs as well as other pathogen associated negative clinical outcomes in patients undergoing allo-HSCT. SER-155 is a live biotherapeutic candidate designed to prevent frequent, expensive, and fatal infections in blood cancer patients.

SER-155 contains 16 bacterial strains selected using our reverse translation discovery and development platform technologies to optimize SER-155's targeted profile. The design incorporates biomarker data from human clinical data and screening data from nonclinical human cell-based assays and in vivo disease models. The bacteria consortia is designed to optimize: (i) the prevention of the growth of various *Enterococcaceae* and *Enterobacteriaceae* species known to potentially dominate the GI tract and lead to downstream negative clinical outcomes in medically compromised patients and that can harbor antibacterial resistance, (ii) the production of multiple bacterial metabolites that can promote mucosal and epithelial barrier integrity with the goal of reducing the likelihood of harmful bacteria translocating from the gut to the bloodstream through a compromised epithelium, and (iii) the production of multiple bacterial metabolites that can modulate immune pathways to induce immune tolerance with a potential impact on GvHD.

The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan Kettering Cancer Center showing that allo-HSCT patients with decreased diversity of commensal microbes and pathogen domination in the GI tract were significantly more likely to die due to infection and/or lethal GvHD (Peled et al., 2020). There are an estimated 40,000 allo-HSCT procedures annually worldwide, and infection is one of the most common causes of mortality in these patients. The Center for International Blood & Marrow Transplant Research, or CIBMTR, reports that 19-28% of deaths in allo-HSCT patients over 18 years of age within 100 days post-transplant are caused by infections and 5-14% by GvHD. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in allo-HSCT patients. In December 2024, the FDA granted Breakthrough Therapy designation for SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT.

SER-155 Phase 1b Study (including placebo-controlled Cohort)

SER-155 has been evaluated in a Phase 1b study in patients undergoing allo-HSCT. The SER-155 Phase 1b study included two cohorts. Cohort 1 was designed to assess safety and drug pharmacology, specifically the drug strain engraftment in the GI tract. Cohort 1 included 13 subjects who received any dosing of the SER-155 regimen, with 11 subjects subsequently receiving an allo-HSCT. Results from this cohort, announced in May 2023, showed SER-155 was generally well tolerated and resulted in successful drug strain engraftment and a reduction in pathogen domination in the GI microbiome relative to a historical control cohort.

Study Cohort 2 utilized a randomized, double-blinded 1:1 placebo-controlled design to further evaluate safety and drug strain engraftment, as well as key secondary and exploratory endpoints such as the incidence of bacterial bloodstream infections and related medical consequences such as febrile neutropenia and antibiotic use. Cohort 2 included 45 patients in the intention-to-treat (ITT) population. Of the ITT population, 20 received SER-155 and 14 received placebo, each of whom subsequently received an allo-HSCT, with data available for clinical evaluation through day 100, the study's prespecified primary observation point. Exploratory hypothesis testing was conducted at the two-sided α=0.05 level. Ninety-five percent (95%) 2-sided confidence intervals (CIs) were determined, where specified. No adjustment for multiplicity was done. A subset of patient samples was available for drug pharmacology analysis.

The median age in Cohort 2 was 63, and most subjects had acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome or myeloproliferative neoplasia as their primary disease and received reduced-intensity conditioning pre-transplant. Most patients received peripheral blood stem cells from a matched unrelated donor. A majority received post-transplant cyclophosphamide as part of their GvHD prophylaxis.

Results from Cohort 2, announced in September 2024, were consistent with the observations from Cohort 1. SER-155 was generally well tolerated, and no treatment-emergent serious adverse events related to drug were observed. SER-155 bacterial strains engrafted into the gastrointestinal tract of patients following the administration of SER-155.

The incidence of BSIs was significantly lower in the SER-155 arm compared with the placebo arm (2/20 (10%) vs. 6/14 (42.9%), respectively; [Odds Ratio: 0.15; 95% CI: 0.01, 1.13, p=0.0423]), which represents a relative risk reduction of approximately 77% and an absolute risk reduction of approximately 33%. In addition, while treatment antibiotic starts were similar in each arm, patients administered SER-155 were treated with antibiotics for a significantly shorter cumulative duration compared to patients in the placebo arm (9.2 days vs. 21.1 days, respectively, with a mean difference of -11.9 days [95% CI: -23.85, -0.04; p=0.0494]). The incidence of febrile neutropenia was lower in patients administered SER-155 compared to placebo (65% vs. 78.6%, respectively; [Odds Ratio: 0.51; 95% CI: 0.07, 2.99; p=0.4674]). Six cases of GI infections (C. difficile infections) were observed in the study, with four cases (20%) in the SER-155 arm and two cases (14.3%) in the placebo arm.

Recent changes in the allo-HSCT standard of care and the increasing use of post-transplant cyclophosphamide as part of prophylactic therapy for GvHD have reduced rates of GvHD overall in this patient population. The rates of GvHD in the study were low, with two cases of grade 2 GvHD observed in each arm, and no cases of grade 3 or 4 GvHD were observed.

In Cohort 2, the ability to detect pathogen domination (i.e., relative abundance in the GI ≥30%) in the placebo arm, and differences between the study arms, was constrained due to the limited number of placebo stool samples and an imbalance in the number of available stool samples between the arms. Observed pathogen domination events were low in the placebo and SER-155 arms with no significant differences identified. In a comparison of the prevalence of pathogen domination versus a larger allo-HSCT historical control cohort, pathogen domination in SER-155 subjects was substantially lower, providing further evidence of SER-155 activity.

We believe the available study data from Cohort 1 suggest that SER-155 administration results has the potential to significantly lower incidence rates of gastrointestinal dominations with pathogens of clinical concern, such as *Enterococcaceae*, *Enterobacteriaceae*, *Streptococcaceae*, and *Staphylococcaceae*. We further believe the resulting Cohort 2 data, together with the Cohort 1 SER-155 Phase 1b study results provide encouraging evidence to support further development of SER-155 to potentially reduce GI associated bloodstream and AMR infections as well as increase immune tolerance in individuals undergoing allo-HSCT for cancers and other serious conditions.

Proposed SER-155 Phase 2 Study

The SER-155 Phase 2 study will incorporate a well-powered, placebo-controlled design, which provides for a planned interim analysis to enable an expedited initial data readout. The SER-155 Phase 2 study is expected to enroll approximately 248 participants and incorporate an adaptive design and an interim data analysis when approximately half of the enrolled participants have reached the primary endpoint. We expect to obtain the interim clinical results within twelve months following study initiation, which we believe will facilitate timely engagement with the FDA on the design of a Phase 3 study and inform development in adjacent medically vulnerable patient populations. We believe that positive results, if achieved, from the Phase 2 study could enable advancement into a single Phase 3 trial to support registration.

Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HSCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with our CRO, and manufacturing of drug substance, we have paused additional investment in that program while continuing to seek funding for the Phase 2 study.

We continue our efforts to obtain capital and other resources to support further development of SER-155 and our broader portfolio of live biotherapeutic product candidates with applications for inflammatory diseases. We are evaluating a range of potential deal structures that we believe could leverage our live biotherapeutics expertise and success, as demonstrated by bringing VOWST from early development through FDA approval.

In October 2025, we presented new post hoc data from our SER-155 Phase 1b trial in an oral presentation at IDWeek in Atlanta, Georgia. The presentation included new post-hoc analysis from the completed SER-155 Phase 1b study describing differences between the SER-155 and placebo groups, including the bacterial and fungal organisms causing BSIs, BSI event clinical outcomes, antibacterial prophylaxis use, and patterns of AMR among the bacterial BSI organisms. These new data illustrated that BSIs occurred despite antibacterial prophylaxis, and that BSI bacteria exhibited AMR. Resistance to multiple antibacterial agent classes was observed only in the BSI bacteria from placebo-treated participants, two of whom had fatal outcomes related to their BSIs. These new data further support the potential of SER-155 as an innovative alternative approach to the significant unmet medical need for prevention of BSIs in HSCT patients, especially those BSIs associated with AMR that increases the risk of morbidity and mortality.

Exploratory biomarker data

In January 2025, we reported exploratory translational biomarker data from the SER-155 Phase 1b study which provided evidence supporting the intended therapeutic mechanisms, including promotion of intestinal epithelial barrier integrity to reduce the potential of bacterial translocation into the bloodstream, and reduction of systemic inflammatory responses. Results from this exploratory biomarker analysis showed that SER-155 was associated with lower levels of fecal albumin and lower concentrations of various plasma biomarkers associated with systemic inflammation (i.e., IFN-y, TNF-α, IL-17, and IL-8) in the HSCT peri-transplant period, the period from the end of the first SER-155 treatment course through to neutrophil engraftment. The results support SER-155's intended mechanisms of action and reinforce the previously reported promising clinical study efficacy and safety data. These systemic inflammatory response observations further support the potential to develop our live biotherapeutics to address inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

In February 2025, clinical and biomarker results from our biotherapeutic programs were presented as a poster at the 2025 Tandem Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and Center for International Blood and Marrow Transplant Research (CIBMTR). SER-155 Phase 1b clinical study data were also featured in an oral presentation in the Best Abstracts in Infectious Diseases track at the Tandem meeting.

In April 2025, we presented SER-155 Phase 1b clinical and exploratory biomarker results at the 51st annual meeting of the

European Society for Blood and Marrow Transplantation, or EBMT. Our presented poster was recognized by the EBMT scientific organizing committee and obtained the "Best Clinical Poster Award."

In May 2025, we presented data at the Digestive Disease Week, or DDW conference highlighting preclinical and clinical data that enable identification of patients with a disease etiology linked to the gastrointestinal microbiome, and the identification of microbiome-based biomarkers that are predictive of response and suitable for patient selection and stratification in clinical trials. Our poster, entitled "Candidate Biomarkers of Microbiome Disruption for Patient Selection or Stratification in Clinical Trials of Microbiome Therapies in Ulcerative Colitis" received a Poster of Distinction award in the Microbiome and Microbial Therapies subgroup. We believe that the data generated suggest that live biotherapeutics could provide a novel treatment modality that could benefit patients living with gut-related inflammatory and immune diseases that are not effectively addressed today. Furthermore, research indicates that specific patient subpopulations optimally suited for biotherapeutic-based treatments may be identifiable. We are exploring options, including potential partnerships, to advance the development of our biotherapeutics in inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

In May 2025, we presented new exploratory biomarker data from the SER-155 Phase 1b study in a poster session at the 2025 American Society of Clinical Oncology, or ASCO, Annual Meeting. The biomarker data presented at ASCO demonstrate the potential of SER-155 to promote immune reconstitution following allo-HSCT by modulating homeostatic cytokines and peripheral T-cell expansion. In post hoc analyses from the SER-155 Phase 1b study, significantly higher levels of the homeostatic cytokine IL-7 were observed both after the second course of SER-155 (administered after neutrophil recovery) and at HSCT Day 100, as compared to placebo. Additionally, a higher frequency of CD4+ T cells was observed in peripheral blood at these same timepoints in the SER-155 arm. We believe the results support the ability of SER-155 to promote peripheral T-cell recovery and immune reconstitution to support favorable outcomes post allo-HSCT.

We believe that exploratory biomarker data presented at recent medical meetings have supported the intended mechanisms of SER-155 and demonstrated the broader potential of live biotherapeutics in inflammatory and immune mediated diseases.

Oral Live Biotherapeutic Product - Liquid Formulation (LBP-LF)

In July 2025, we were awarded a grant from CARB-X to support the development of an oral liquid formulation of an LBP based on SER-155 (LBP-LF) for medically vulnerable patient populations at risk of BSIs, including AMR infections, who cannot be dosed with oral capsules, such as intubated patients in the ICU. The CARB-X grant provides us with up to $3.6 million of funding for research, manufacture, and design of a Phase 1 clinical trial in ICU patients. LBP-LF is designed to target the prevention of bloodstream infections in medical ICU patients by *Escherichia coli* and other gut-derived bacteria capable of harboring antibiotic resistance.

Up to 50% of all preventable medical ICU deaths have been attributed to infections with *E. coli* and other gut-derived bacteria (Mayr, 2006). These infections are also the leading cost in the medical ICU (Neidell, 2012). When ICU patients with multidrug resistant, or MDR, infections survive hospitalization, they have high long-term morbidity with over 20% 30-day readmission rates (Chang, 2015; Mayr, 2017). Over 5 million patients are admitted to ICUs in the U.S. annually, and these admissions account for approximately 20% of all acute care hospitalizations (Barrett et al. 2024). Infections with pathogenic, often MDR, bacteria are the leading cause of mortality in the medical ICU, causing up to 9 deaths for every 100 ICU patients admitted (Vincent, 2009). Most patients are admitted to the medical ICU with a known or suspected infection (i.e., sepsis) but, with targeted or empiric antibiotics, most recover from this initial infection. Once in the ICU, secondary, healthcare-associated infections frequently develop during the prolonged recovery from sepsis and are a significant driver of mortality.

LBP-LF is a novel approach that addresses both gut colonization and subsequent translocation by *E. coli* and other gut-derived pathogens to prevent a significant proportion of these secondary hospital acquired infections. LBP-LF is in preclinical development, with IND-enabling activities ongoing and IND-readiness targeted by the end of 2026. Development of LBP-LF is ongoing with grant support from CARB-X and in collaboration with Columbia University.

SER-147

We are also developing another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including chronic liver disease, or CLD. SER-147 was designed and optimized using our reverse translational therapeutics development platform.

CLD is a progressive condition marked by deterioration of liver function and is reaching epidemic proportions affecting nearly 1.7 billion people worldwide, causing substantial health burden on afflicted countries (GBD 2017 Cirrhosis Collaborators, 2020, Clinical Liver Disease, 2021). In the advanced stages of CLD, known as decompensated cirrhosis, patients exhibit significant immune dysfunction, microbiome disruption, and increased contact with the healthcare system, all of which drive increased susceptibility to bacterial infections such as SBP and BSIs (Bajaj et al., 2021, Albillos et al., 2022). Over 40% of patients with decompensated cirrhosis experience an infection within the first year of diagnosis. Antibiotics are the only prophylactic option for patients at high risk of infections like SBP, resulting in exposure to antibiotics for months or years. To combat increasing rates of AMR, antibacterial prophylaxis for primary SBP is no longer recommended for the majority of patients outside of very high-risk, leaving significant

unmet need. Many cultivated live biotherapeutics currently in clinic are constrained by formulation technologies incompatible with concomitant medications commonly used in CLD.

SER-147 is in preclinical development. The program is ready to progress to IND-enabling activities, including manufacturing, in order to advance to clinical development.

Manufacturing

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

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

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

We have cGMP manufacturing capabilities at our Cambridge, Massachusetts locations where we conduct cGMP manufacture of therapeutic candidates to support both drug substance and drug product manufacturing for early-phase and late-phase clinical development. Our current live biotherapeutic pipeline assets, including SER-155 and SER-603, are manufactured from standard clonal cell banks via cultivation. We may establish further manufacturing capabilities and 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

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

Intellectual Property

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

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

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

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

Our patent portfolio includes issued U.S. patents and patent applications in various stages of prosecution, including ex-U.S. international counterparts. We believe that issued claims will provide protection for our live biotherapeutic 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 live biotherapeutics, 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 live biotherapeutic which will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of lower cost products.

Government Regulation

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

In the United States, the FDA regulates drug and biologic products under the Federal Food, Drug and Cosmetic Act, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates are subject to regulation by the FDA as biologics. Biologics require the submission of a BLA and approval by the FDA before being marketed in the United States.

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

- completion of certain preclinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials in the United States may begin;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before a trial is commenced;

- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the product candidate for each proposed indication, conducted in accordance with the FDA's good clinical practice, or GCP, regulations;
- preparation and submission to the FDA of a BLA after completion of all pivotal trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the product.

Preclinical and Clinical Trials

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

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

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

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

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

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

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

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

BLA Submission and FDA Review

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

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

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

Once a BLA has been accepted for review, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for Priority Review, six months after the FDA accepts the application for filing, but the overall timeframe may be extended for a period of three months for FDA to respond to new information deemed a "major amendment" to the application. The FDA reviews a BLA to determine, among other things, whether the biological product is safe, pure and potent and whether the facility or facilities in which it is manufactured meet standards designed to assure the product's continued safety, purity and potency.

The FDA may also refer the application to an Advisory Committee for review, evaluation, and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving a BLA, the FDA will typically inspect the facility or the facilities at which the biologic product is manufactured and will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure that such trials were conducted in compliance with GCP.

After the FDA evaluates a BLA and conducts any required inspections of clinical trial sites or manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its

present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

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

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

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

Any product candidate submitted to the FDA for approval, including a product candidate with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review process, including Priority Review designation. A BLA is eligible for Priority Review if the product candidate has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, depending on the design of the applicable clinical trials, product candidates are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is usually contingent on a sponsor's agreement to conduct confirmatory studies to verify and describe the product's clinical benefit, and the FDA may require that such studies be underway before granting any accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA 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 letters, 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 and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Biosimilars and Regulatory Exclusivity

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

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective

by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

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

Orphan Drug Designation

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

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

Government Regulation Outside of the United States

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

Non-clinical studies and clinical trials

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

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

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

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

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

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

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

Marketing Authorizations

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

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

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

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

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

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

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

Data and Marketing Exclusivity

In the EU, upon receiving a MA, reference medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of the market exclusivity period a generic or biosimilar MA can be submitted, and the innovator's data may be referenced but no generic or biosimilar can be marketed in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing

therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

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

Orphan Medicinal Products

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

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

Pediatric Development

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

Post-Approval Requirements

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

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

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

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

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

Brexit and the Regulatory Framework in the United Kingdom

Since the end of the Brexit transition period on January 1, 2021, and the implementation of the Windsor Framework on January 1, 2025, the United Kingdom, or UK, is not generally subject to EU laws in respect of medicinal products. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK. However, new legislation such as the CTR is not applicable in the UK. The UK government has passed the Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone medicines and medical devices regulator. As a result of the Ireland/Northern Ireland Protocol, different rules applied in Northern Ireland than in England, Wales, and Scotland, together, Great Britain ("GB"); which continued to follow the EU regulatory regime. However, on January 1, 2025, an arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes, and EU labeling and serialization requirements in relation to Northern Ireland, and introduces a UK-wide licensing process for medicinal products.

MAs in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. In order to use the EU centralized procedure to obtain an MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore, since Brexit, companies established in the UK cannot use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicinal products that will benefit patients, including a 150-day assessment (subject to clock-stops) and a rolling review procedure. In addition, an international recognition framework, or IRP, has been in place since January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new UK MA. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulators in Australia, Canada, Switzerland, Singapore, Japan, the U.S. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update an MA in the UK. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60-day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval has not been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals. In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the medicinal product on the market in the UK within three (3) years shall cease to be in force. There is no pre-MA orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in the UK.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical and biological products, other healthcare regulatory laws restrict business practices in the biotechnology industry, which include, but are not limited to, anti-kickback, false claims, and transparency laws regarding drug pricing and payments and other transfers of value made to physicians and other healthcare providers.

The federal Anti-Kickback Statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly interpreted to include anything of value, including cash, improper discounts and free or reduced-price items and services. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Many states have similar laws that apply to their state healthcare programs as well as private payors.

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

In addition, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties for each wrongful act. Moreover, in certain cases, providers who routinely waive copayments and deductibles for

Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and civil False Claims Act, which can impose additional penalties associated with the wrongful act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of the Department of Health and Human Services emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud.

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

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

To the extent that 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 regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system. It is uncertain what legislative or regulatory 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, the ACA was enacted in 2010, 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:

- imposed an annual, nondeductible fee payable by an entity that manufactures or imports specified branded prescription drugs and biologic agents;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- extended manufacturer Medicaid drug rebate liability from fee-for-service utilization to include Medicaid managed care utilization;
- expanded the entity types eligible for participation in the 340B drug pricing program; and
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, among other things, included reductions of Medicare payments to providers, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021 eliminated the statutory cap on drug manufacturers' Medicaid drug rebate program liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. The Inflation Reduction Act ("IRA") was enacted in 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (which began in 2024); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate that we commercialize. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S pharmaceutical sector and our business.

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, marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. Some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for our investigational products that receive approval. Adoption of other new legislation or regulation at the federal, state, or foreign level could further limit reimbursement for pharmaceuticals, including our product candidates if approved.

Data Privacy and Security

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

health information privacy and security laws and consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information.

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

Human Capital

Employees

As of December 31, 2025, we had 66 full-time permanent employees, which included 14 employees in operations and administration and 52 employees in research and development (which includes clinical and manufacturing). Following the implementation of cost reduction actions in February 2026, our headcount was further reduced to 45 employees, including 13 in operations and administration and 32 employees in research and development as of March 1, 2026. None of our employees in the U.S. are currently represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Talent Acquisition and Development

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

Inclusion and Belonging

We also believe that our long-term success and ability to deliver innovative, safe, and effective medicines to patients requires an inclusive workforce. We work to identify ways to attract, develop, and retain talent from all backgrounds and help foster a stronger sense of belonging for all employees. In addition, we strive to engender an open culture of mutual respect, and one that values employees' health and well-being. We support employee development in a variety of ways including leadership training to build people manager capabilities, ongoing performance and development conversations, and tuition reimbursement. Our management reports to our Board on human capital management topics, including as relevant: corporate culture, workforce inclusion and belonging, employee development and retention, and compensation and benefits.

Our Corporate Information

We were incorporated in the State of Delaware in 2010 under the name Newco LS21, Inc. In October 2011, we changed our name to Seres Health, Inc., and in May 2015, we changed our name to Seres Therapeutics, Inc. Our principal executive offices are located at 101 Cambridgepark Drive, Cambridge, Massachusetts 02140 and our telephone number is (617) 945-9626. Our website address is *www.serestherapeutics.com*. The information contained in, or accessible through, our website does not constitute a part of this Annual Report on Form 10-K.

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

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

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Need for Additional Capital

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

Based on our currently available cash resources, and considering our future operating plans, we anticipate that we will require additional funding following the third quarter of 2026. The ability to obtain additional equity or other financing, including through partnerships, with terms favorable or acceptable to us cannot be considered probable according to the applicable accounting standards because they are outside our control. Therefore, there is substantial doubt about our ability to continue as a going concern for at least 12 months from the date that our consolidated financial statements for the year ended December 31, 2025 were issued. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing or enter into a partnership. If potential collaborators or partners decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our audited consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments to reflect the possible inability of the Company to continue as a going concern within 12 months after the issuance of such financial statements.

We will need additional funding in order to advance development of our product candidates (including to conduct the planned Phase 2 study of SER-155 in allo-HSCT and to advance our earlier stage programs) and commercialize our product candidates, if approved. If we are unable to raise capital or secure a partnership or other business development transaction, we could be required to implement further cost-reduction measures, reduce or delay our product development programs or any potential future commercialization efforts, or pursue other alternatives which could include seeking relief under the U.S. Bankruptcy Code or winding down our operations.

Our expenses may increase in connection with our ongoing activities, particularly if we further SER-155 clinical studies, and research, develop and initiate clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including marketing, sales and distribution, and may not generate meaningful product revenues or collaboration profit in the near future. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or secure a partnership when needed or on attractive terms, we could be forced to reduce or delay our product development programs or potential future commercialization efforts, or pursue other alternatives, which could include seeking relief under the U.S. Bankruptcy Code or winding down our operations.

We are actively seeking a business development transaction, which may include a partnership, to provide financial support and share in our vision to realize the clinical and commercial value of SER-155. Our strategic discussions are focused on supporting SER-155 clinical advancement to reduce the risk of bloodstream infections, including life-threatening and AMR infections, in medically vulnerable patient populations. We believe that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations beyond allo-HSCT, including autologous-HSCT patients, cancer patients with neutropenia, CAR-T recipients, individuals with chronic liver disease, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities. We are also exploring collaborations to advance the development of our investigational biotherapeutics in inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

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

- the cost of developing our pipeline product candidates, including SER-603 in IBD and SER-155 in irEC
- the cost of conducting clinical trials for SER-155 in allo-HSCT and other targeted indications, and other product candidates in our pipeline;
- the total amount of the Milestone Payments we may receive from the Transaction;
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additionally, market volatility resulting from current macroeconomic conditions, such as the conflicts involving Ukraine and Russia and Israel and its surrounding regions, trade wars or related uncertainty between the U.S. and other nations, including China, or other governmental action related to tariffs or international trade agreements or policies, and related impacts, 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 any product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially adversely affect our business, financial condition and results of operations. We may pursue strategic partnerships or collaborations or other alternatives with one or more parties. We can provide no assurance that we will be successful in securing any strategic partnership, collaboration, or alternative, or that any such partnership, collaboration or alternative that we secure will achieve its intended benefits or have a positive impact on our financial condition or business.

We are a clinical-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 loss from operations was $94.0 million, $121.3 million, and $195.1 million for the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, we had cash and cash equivalents totaling $45.8 million and an accumulated deficit of $972.4 million. As noted elsewhere in this Annual Report on Form 10-K, we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. To date, we have financed our operations through the public offerings of our common stock, private placements of our common stock and preferred stock, payments under our prior collaboration agreements and loan facility and payments from government entities for research grants. We have devoted substantially all of our financial resources and efforts to developing our live biotherapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have only developed one FDA-approved product, VOWST, which was sold to SPN in September 2024. We have not completed development of any of our other product candidates, which we call live biotherapeutic candidates, or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our expenses may increase substantially in connection with our ongoing and future activities, particularly if and as we:

- invest in our early-stage pipeline product candidates, including SER-603 in IBD and SER-155 in irEC;
- conduct clinical trials for SER-155 in patients receiving allo-HSCT and for other medically vulnerable populations;
- advance research and development activities supported by partnerships;
- make strategic investments in manufacturing capabilities;
- maintain and augment our extensive proprietary live biotherapeutic drug development know-how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire;
- establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we have obtained and in the future may obtain regulatory approval;
- perform our obligations under any agreements with collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

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

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

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

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

Since our inception in October 2010, we have devoted substantially all of our resources to developing our clinical and preclinical program, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. Other than with respect to VOWST, which was sold to SPN in September 2024, we have not yet demonstrated our ability to obtain regulatory approvals, and we have limited experience in demonstrating our ability to manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, including for example, the impact of the sale of our VOWST Business to SPN, 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.

The total amount of the Milestone Payments we may receive from the Transaction is subject to various risks and uncertainties.

In connection with the Closing, SPN assumed certain liabilities with respect to the VOWST Business and agreed to pay to us, among other payments:

- cash installment payments of $50 million, which was received on January 15, 2025, and $25 million, which was received July 1, 2025, (offset by $1.4 million paid by us to Nestlé on July 1, 2025 related to certain employment obligations assumed by SPN, as described below), conditioned on our material compliance with obligations under the TSA entered into at Closing between us and NESA;
- prepayment of the $60 million Prepaid Milestone tied to the achievement of the First Sales Milestone of worldwide annual net sales of the Product of $150 million, which was paid in cash at Closing, which Prepaid Milestone will accrue interest at a fixed rate of 10% per annum until the First Sales Milestone is achieved and 5% per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set-off and (y) the last day of the Milestone Period; and
- future Milestone Payments of (x) $125 million tied to the achievement of worldwide annual net sales of the Product of $400 million and (y) $150 million tied to the achievement of worldwide annual net sales of the Product of $750 million, during the Milestone Period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs.

As they are earned, the Milestone Payments will be satisfied as follows: (1) first, by set-off against all accrued interest on the Prepaid Milestone, (2) second, by set-off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (3) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period, the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set-off of SPN with respect thereto will be deemed forfeited. The installment payment received on July 1, 2025 was offset by $1.4 million we paid to Nestlé on the same date related to certain employment obligations assumed by SPN through the period prior to the Closing Date. Further, during the Profit Sharing Period, we and SPN shared 50/50 in the net profit or net loss achieved during the period.

The Milestone Payments are subject to various risks and uncertainties. The Milestone Payments are based on the achievement of specified worldwide net sales targets for the Product. Interest on the Prepaid Milestone will accrue and will reduce any corresponding Milestone Payments based on the length of time it takes to achieve the milestones. It is not possible to determine with precision as of the date of this Annual Report on Form 10-K the amount or timing of worldwide net sales the Product will generate in the future and, therefore, it is possible that certain of the Milestone Payments will not be earned or will be limited by lower Product net sales than anticipated. The specified worldwide net sales targets for the Product were based on certain assumptions about the future financial performance of the Product, and there can be no assurance that such projections will be achieved or that certain of the Milestone Payments will become payable.

We may not be able to realize the anticipated benefits of the Transaction, and we may face new challenges as a smaller, less diversified company.

We may not be able to realize the anticipated benefits from the Transaction, including deploying the proceeds from the Transaction to advance SER-155 and support our pipeline of wholly-owned cultivated live biotherapeutic candidates. Our ability to realize the anticipated benefits of the Transaction and the success of the remaining company is subject to various risks and uncertainties, including the possibility that we may not be able to successfully use our live biotherapeutics platform to build a pipeline of product candidates and develop additional marketable drugs, and the possibility that we will not be able to obtain, or experience delays in obtaining, required regulatory approvals.

The Transaction resulted in the Company being a smaller, less diversified company with a more limited remaining business concentrated on SER-155, which recently completed a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation, and our other wholly-owned cultivated live biotherapeutic candidates. As a result, we may be more susceptible to changing market conditions, including fluctuations and risks particular to preclinical and clinical-stage companies, than a more diversified company, which could adversely affect our remaining business, financial condition and results of operations. In addition, the diversification of our costs and cash flows diminished following the Transaction, such that our results of operations, cash flows, working capital and financing requirements may be subject to increased volatility and our ability to fund capital expenditures and investments or satisfy other financial commitments may be diminished.

We will need to secure additional funding to maintain operations beyond our current cash runway. Based on our currently available cash resources, and considering our future operating plans, we anticipate that we will require additional funding following the third quarter of 2026. However, due to our smaller business size and the early stage of development of our remaining assets, there can be no assurance that we will be able to raise the required capital on favorable terms, or at all. This potential inability to obtain necessary funding could have a material adverse effect on our growth prospects, financial condition, and results of operations.

We may also face new challenges with maintaining employee morale and retaining key management and other employees and retaining existing business and operational relationships, including with third parties, employees and other counterparties that otherwise prefer to transact with larger companies (or will only transact with smaller companies on less favorable terms).

We have broad discretion as to the use of the proceeds from the Transaction, and may not use the proceeds effectively.

We were obligated to use the proceeds from the completion of the Transaction to fully repay our indebtedness under our prior credit facility with Oaktree Capital Management ("Oaktree"). We have broad discretion with respect to the use of the remaining proceeds of the Transaction, including to support the further advancement of SER-155 and our other cultivated live biotherapeutic product candidates. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that do not improve our remaining business, financial condition or results of operations. Our failure to apply these funds effectively could have an adverse effect on its business, financial condition and results of operations.

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

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

We are using our reverse translational platform to develop live biotherapeutic candidates. We are at an early stage of development of our product candidates and our platform may never lead to approvable or marketable drugs. We are developing product candidates that are designed to reduce infection and treat diseases where the microbiome is implicated. We may have problems applying our technologies to these areas, and our product candidates may not be effective in reducing infection and disease. Our product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and, if approved, achieve market acceptance.

The success of our product 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 product candidates, 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 product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates, 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 product candidates, if approved, following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our product candidates and technology.

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

Our product candidates are based on live biotherapeutics, which is a novel approach to therapeutic intervention.

Our product candidates are based on live biotherapeutics, a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. To our knowledge, VOWST is the first oral product based on this approach to receive FDA approval. We cannot be certain that our approach will lead to the development of additional approvable or marketable products or that we will be able to manufacture at commercial scale. Finally, the FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of novel product candidates based on live biotherapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent any potential future 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 potential future 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 product candidates. Prior to approving a new therapeutic product, the FDA (or other regulatory authorities) generally requires that safety and efficacy, or with respect to biological products such as our live biotherapeutic candidates, safety, purity and potency, be demonstrated in two adequate and well-controlled clinical trials. In some situations, evidence from a Phase 2 trial and a Phase 3 trial or from a single Phase 3 trial can be sufficient for FDA approval, such as in cases where the trial or trials provide highly reliable and statistically strong evidence of an important clinical benefit.

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

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

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

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

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

In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

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

The UK regulatory framework in relation to clinical trials is derived from the now-repealed EU Clinical Trials Directive (as implemented into UK law, through the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended). In April 2025, the UK government adopted the Medicines for Human Use (Clinical Trials) Amendment Regulations. The amendment, which will take full effect in April 2026, aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered.

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

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

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

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

Patient enrollment is also affected by other factors including:

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

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

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

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

our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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

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

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

Our product candidates and the activities associated with their development and potential future commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us and any collaborators from commercializing the product candidate in that jurisdiction and may affect our plans for potential future 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, or with respect to biologics such as our live biotherapeutic candidates, safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, risky and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our live biotherapeutic candidates. The FDA or foreign regulatory authorities may delay, limit, or deny approval to market our product candidates for many reasons, including: our inability to demonstrate that the clinical benefits of our product candidates outweigh any safety or other perceived risks; the regulatory authority's disagreement with the interpretation of data from nonclinical or clinical studies; the regulatory authority's requirement that we conduct additional preclinical studies and clinical trials; changes in marketing approval policies during the development period; changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application; or the regulatory authority's failure to approve the manufacturing processes or third-party manufacturers with which we contract. For instance, the EU pharmaceutical legislation has been undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. A provisional agreement has been reached by the European Parliament and Council of the EU on the proposed revisions on December 11, 2025. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the two institutions, which is not anticipated before early 2026. The proposed changes are not expected to enter into application before 2028 and may however have a significant impact on the biopharmaceutical industry in the long term.

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

Furthermore, our product candidates may not receive marketing approval even if they achieve their specified endpoints in clinical trials. Clinical data are often susceptible to varying interpretations and many companies that have believed that their products

performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory authority approval for their products. The FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from nonclinical and clinical studies, or they may require additional confirmatory or safety evidence beyond our existing clinical studies. Upon the FDA's review of data from any pivotal trial, it may request that the sponsor conduct additional analyses of the data or gather more data and, if it believes the data are not satisfactory, could advise the sponsor to delay submitting a marketing application.

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

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

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

We have and may in the future seek Fast Track designation for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for Fast Track designation. We received Fast Track designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Once granted, Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, and a BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

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

A Breakthrough Therapy, or other similar designations 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.

In December 2024, we received Breakthrough Therapy designation for SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. We may seek these or other designations for future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed in early clinical development. For drugs or biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA also receive all of the Fast Track program features, including eligibility for rolling review of the associated marketing application.

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

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

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

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

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

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

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

We may seek orphan drug designation for some of our future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or other regulatory authorities from approving another marketing application for the same drug and same disease or condition during that time period, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. The applicable period is seven years in the United States and ten years in the EU. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a product no longer meets the criteria for orphan designation, if the product is sufficiently profitable so that market exclusivity is no longer justified, or the prevalence of the condition has increased above the orphan designation threshold. Orphan drug exclusivity may be lost if the FDA or other regulatory authorities determine that the request for designation was materially defective or if the manufacturer is unable to assure a sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity for a product may not effectively protect the product from competition because different drugs and biologics can be approved for the same disease or condition. Even after an orphan drug or biologic is approved, the FDA or other regulatory authorities can subsequently approve the same drug or biologic for the same disease or condition if the FDA or other regulatory authorities conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes

a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time nor gives the drug any advantage in the regulatory review or approval process.

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

The ability of the FDA and other regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's and other regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's and other regulatory authorities' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities, such as the EMA, 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, in recent years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations, or changes in administrative policy delay or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. It could also impact our ability to access the public markets and obtain necessary capital in order to fund our operations.

Risks Related to our Dependence on Third Parties and Manufacturing

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

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

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

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

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or potential commercialization of our products, if and when approved, 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, and we expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or potential future 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 potential future commercialization efforts.

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

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

Third-party manufacturers may not be able to comply with current good manufacturing processes, or cGMP, regulations or similar regulatory requirements inside or outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if and when approved. If our manufacturers are unable to comply with cGMP regulation or similar regulatory requirements outside the United States or if the FDA or other regulatory authorities do not approve their facility upon a pre-approval inspection, our therapeutic candidates may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and similar regulatory requirements outside the United States that might be capable of manufacturing our products, if and when approved. 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 potential future commercialization of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Furthermore, if we breach or are perceived to breach our contractual obligations or otherwise default under our agreements with third parties, or if we otherwise have contractual disputes with such third parties, it may lead to adverse outcomes, including potential delays, unforeseen expenses, or the termination of those contracts. We do not currently have a second source for certain required materials used for the manufacture of finished product. If our current manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and potential future commercialization efforts.

Evaluation of our product candidates in investigator-sponsored clinical trials (ISTs) may expose us to additional risks that could impair the development of our product candidates.

We are currently supporting an IST with Memorial Sloan Kettering Cancer Center to evaluate SER-155 in patients with immune checkpoint related enterocolitis, and may in the future support other ISTs for our product candidates that are designed and managed by independent investigators or institutions. While we believe these clinical trials have the potential to provide supportive data that may further the development of our product candidates, we do not directly control the clinical development process, including, but not limited to, the initiation, enrollment, safety reporting, or conduct of these trials. As a result, ISTs may be subject to significant delays, fail to comply with GCPs or other regulatory requirements, be terminated prematurely by the investigator or applicable IRBs or ethics committees, or produce data that is not useful for, or acceptable to, regulatory authorities for purposes of obtaining regulatory approval. ISTs may also identify safety or tolerability concerns that could adversely affect the development of our product candidates, including through the imposition of clinical holds, or otherwise subject us to liability. Moreover, if the data from any ISTs differ from the data we have observed in our sponsored clinical studies, such differences could potentially require us to conduct additional clinical trials or otherwise delay or prevent regulatory approval from the FDA or other regulatory authorities. Any of these factors could adversely impact our reputation, delay our development timelines, or negatively affect our development and commercialization efforts.

We have limited experience manufacturing our product candidates commercially, and we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have manufacturing facilities at our Cambridge, Massachusetts locations where we conduct process development, scale-up activities, the manufacture of active components for our biotherapeutic candidates, and quality control testing. We additionally utilize third-party contract manufacturers and test labs to perform product packaging and additional quality control testing. We may or may not utilize existing facilities and third-party vendors for future production, including to support commercial scale supply. We have no experience in manufacturing our product candidates to meet potential market demands and we may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for commercial use. The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP or similar regulatory requirements outside the United States. We have not yet had our manufacturing facilities inspected for our product candidates.

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

Risks Related to Our Product Candidates and Other Legal Matters

Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.

Even if any of our product candidates receive marketing approval, our product candidates may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates (if and when they are approved) do not achieve an adequate level of acceptance, we may not become profitable. The degree of market acceptance of any of our product candidates, if approved, will depend on a number of factors, including:

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

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 any of our product candidates if and when they are approved.

We have employees with experience in sales and marketing, but we have limited sales or marketing infrastructure and, as a company, have little experience in the sale, marketing, and distribution of pharmaceutical products. To achieve commercial success for any other product for which we obtain marketing approval, we will need to establish a sales and marketing organization and we may not be successful in doing so.

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

Factors that may inhibit efforts to commercialize our product candidates, if and when approved, include:

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

Outside the United States, we intend to rely and may increasingly rely on third parties to sell, market and distribute our product candidates, if and when approved. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our 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 product candidates, if and when they are approved, 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 or commercialization of products, including live biotherapeutics, for 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. Potential competitors also include academic institutions, government agencies, not-for-profits, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we have or may in the future develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a live biotherapeutic 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 of our product candidates, if approved, the products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, any of which would harm our business.

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

Obtaining and maintaining adequate reimbursement for our product candidates may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our product candidates 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 potential 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 an even greater risk with the commercial sale of 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 product candidates or products, if any;
- 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 products that we develop, if any.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials, or if we commence commercialization of our product candidates, if and when approved. 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.

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

We believe that any of our product candidates approved as a biological product under a BLA should also qualify for the 12-year period of reference product exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

In the EU, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product but will not be able to get on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period can be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our product candidates. If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, our product candidates 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 product candidates in the EU and many other jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We 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 product candidates in any market.

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

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

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

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

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

- litigation involving patients taking our products, if and when they are approved;
- 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, if and when they are approved;
- product seizure or detention;
- injunctions; or
- imposition of civil or criminal penalties.

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

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

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

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

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

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be

made under a federal healthcare program, such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the False Claims Act, imposes, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties;
- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; manufacturers are required to submit reports to the government by the 90th day of each calendar year; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government (or foreign governments) and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, pricing information or marketing expenditures.

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

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

Current and future legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may adversely 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. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, including executive orders, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any product candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations and financial condition.

In the United States, the Affordable Care Act or ACA, was signed into law in 2010. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affects the U.S. pharmaceutical industry.

Among the provisions of the ACA of importance to our business, including without limitation, our ability to commercialize and the prices we may obtain for any product candidates that are approved for sale are the following:

- establishment of a new pathway for approval of lower-cost biosimilars to compete with biologic products, such as those we are developing or commercializing;
- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- extension of manufacturers' Medicaid rebate liability to apply to Medicaid managed care utilization;
- expansion of the entity types eligible for participation in the 340B drug pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Drug manufacturers' Medicaid Drug Rebate Program rebate liability was previously capped at 100% of the average manufacturer price for a covered outpatient drug.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. The Inflation Reduction Act, or the IRA, was enacted in 2022. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (which began in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how these proposals will be implemented, these policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate that we commercialize. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the

units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business.

Individual states in the United States have become increasingly active in enacting laws or 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. Some measures are designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. Some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution.

Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our ability to price our product candidates, if and when they are approved, appropriately, which could negatively impact our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for 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.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

In some countries, particularly the EU member states, the pricing of certain pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various EU member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. If coverage and reimbursement of our product candidates, if and when they are approved, are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels that impacts our ability to compete with other products or our ability to recoup our costs of developing our product candidates, 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 product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

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

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

Our patent portfolio currently includes 22 active patent application families (which includes an exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 18 applications have been nationalized, one is at the PCT stage, and three are at the provisional stage. To date, we have obtained issuance of 33 U.S. patents (which includes three as licensee). Of the issued U.S. patents, 13 U.S. patents (including one as licensee) have been assigned to Nestlé Health Science as part of its purchase of VOWST. We cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and/or their use. However, there can be no assurance that an alternative composition that may fall outside the scope of such claims will not be equally effective. Further, while our product candidates are made up of specific cultivated bacteria, third-party compositions may have greater complexity and variability (e.g., lot to lot variations), and it is possible that a patent claim may provide coverage for some but not all third-party compositions. 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 product candidates. In addition, given the on-going prosecution of our portfolio, we continue development of our understanding of how patent offices react to our patent claims and whether they identify prior art of relevance that we have not already considered.

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

We may be subject to third-party preissuance submissions of prior art to the United States Patent and Trademark Office, or USPTO, or in a foreign jurisdiction in which our applications are filed, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, on April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to

The University of Tokyo. See "*—Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business*." The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Opposition Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our commercial success depends upon our ability, and the ability of any collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. For example, on August 20, 2024, Vedanta Biosciences, Inc. and The University of Tokyo filed a complaint against us and Nestlé S.A., Nestlé Health Science S.A., Nestlé Health Science US Holdings, Inc. and SPN in the United States District Court for the District of Delaware alleging that the making, sale and use of VOWST infringes on U.S. Patent Nos. 9,433,652, 9,662,381, 9,808,519, 10,555,978, and 11,090,343. The complaint seeks unspecified damages, fees, expenses and injunctive relief. We believe the complaint is without merit and intend to defend ourself vigorously against the claims. While we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology or our product candidates, or use of our product candidates do not infringe third-party patents.

We are aware of numerous patents and pending applications owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to 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 or our product candidates. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of our product candidates, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies or our product candidates or the use of our product candidates. We are aware of several pending patent applications containing one or more claims that could be construed to cover some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of third-party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use. On April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Oppositions Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates, or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U.S. patent in court, such as an issued U.S. patent of potential relevance to some of 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 product candidates and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing 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 product candidates. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

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

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

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

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

construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

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

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

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

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

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

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

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

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

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

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we

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

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

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

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

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates 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 product candidates, 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

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

On February 27, 2026, the board of directors appointed Richard N. Kender, a current member of the board of directors, to serve as Executive Chair of the Board and as Interim Chief Executive Officer of the Company, Matthew Henn, Ph.D., the Company's Chief Scientific Officer, to the additional role of President, and Kelly Brady, M.S., the Company's Senior Vice President, Clinical Development, to the role of Executive Vice President, Chief Operating Officer, each effective March 2, 2026 (the "Effective Date"). As a result of the appointment of Mr. Kender as Interim Chief Executive Officer, Thomas J. DesRosier and Marella Thorell ceased serving as Co-Presidents and Co-Chief Executive Officers of the Company as of the Effective Date. Mr. DesRosier continues to serve as the Company's Executive Vice President, Chief Legal Officer, and Ms. Thorell continues to serve as the Company's Executive Vice President, Chief Financial Officer.

Management transitions may create uncertainty and involve a diversion of resources and management attention, be disruptive to our daily operations or impact public or market perception, any of which could negatively impact our ability to operate effectively or execute our strategies and result in a material adverse impact on our business, financial condition, results of operations or cash flows. If we are unable to execute an orderly transition, our business may be adversely affected. Furthermore, the success of our business is dependent on the continuation of an experienced and talented management team. If we were to lose the benefit of the experience, efforts, and abilities of any of our key executives or members of senior management, our business could be adversely affected.

We are highly dependent on our Interim CEO, 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 potential future 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 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 and execution. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

On September 23, 2025, we announced that we implemented cost reduction actions, including decreasing our workforce by approximately 25%. We decreased the workforce by an additional 30% in February 2026 as part of additional cost reduction measures taken to extend our cash runway. These measures could result in personnel attrition beyond our planned reduction in headcount or reduce employee morale, which could in turn adversely impact productivity, including through a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods, or our ability to attract highly skilled employees.

If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

We currently have limited international operations, but our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. We have conducted clinical studies internationally in the past, and will

likely in the future conduct clinical studies in other countries as well. 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, including tariffs, 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 product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- global macroeconomic conditions, including a continued increase in inflation rates or interest rates, labor shortages, supply chain shortages, disruptions and instability in the banking industry and other parts of the financial services sector, or other economic, political or legal uncertainties or adverse developments;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- terrorism and/or political instability, unrest and wars, such as the conflicts involving Ukraine and Russia or Israel and its surrounding regions, which could delay or disrupt our business, and if such political unrest escalates or spills over to or otherwise impacts additional regions it could heighten many of the other risk factors included in this Item 1A;
- natural disasters (including as a result of severe weather events, climate change or otherwise), which could cause significant damage to the infrastructure upon which our business operations rely, and the timing, nature or severity of which we may be unable to prepare for;
- economic instability, outbreak of disease or epidemics, 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.

We have significant excess leased space that may adversely affect our financial condition and results of operations.

Following the sale of our VOWST Business, the completion of the TSA, and our cost reduction actions, we have significantly reduced our workforce and manufacturing footprint. As a result, we have excess capacity under our existing lease obligations that exceeds our current and anticipated operational needs. We remain obligated to make rental and other payments under these leases regardless of whether we utilize the leased space. Our lease obligations require us to make substantial cash payments that reduce the cash available to fund our research and development programs, clinical trials, and other operational needs.

We may seek to sublease the excess space to reduce our ongoing costs; however, there can be no assurance that we will be able to identify suitable subtenants or negotiate sublease arrangements on favorable terms, or at all. Current commercial real estate market conditions, including elevated vacancy rates and declining demand for certain types of office and laboratory space, may make it difficult to sublease our excess space or may require us to accept sublease terms that do not fully offset our lease obligations. Even if we are able to sublease the excess space, we would remain primarily liable to the landlord under the underlying leases, and any default by a subtenant could result in additional costs and liabilities to us.

In addition, we may be required to recognize impairment charges with respect to right-of-use assets associated with leased properties that are no longer being fully utilized. Any such impairment charges could have a material adverse effect on our results of operations and financial condition.

The costs associated with our excess leased space, combined with any inability to sublease such space or potential impairment charges, could materially and adversely affect our liquidity, cash flows, financial condition, and results of operations, and could limit our ability to invest in the advancement of SER-155 and our other pipeline programs.

Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.

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

We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques, including artificial intelligence ("AI"), that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Additionally, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges.

We and certain of our service providers are from time to time subject to cyberattacks and security attempts or incidents that threaten the confidentiality, integrity and availability of our information technology systems and confidential information. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information technology systems or data, the costs associated with the investigation and remediation could be material. Any such real or perceived unauthorized access or use, breach, or other loss of confidential information could also result in regulatory scrutiny, reputational harm, legal claims or proceedings (including class actions), and liability under federal or state laws that protect the privacy of personal information, and regulatory enforcement, including penalties or fines. Notice of breaches may be required to affected individuals or state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such notifications could be costly, harm our reputation and our ability to compete. Although we have implemented security measures to prevent unauthorized access, such data is currently accessible through multiple channels, and there is no guarantee that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and data from breach. Additionally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

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

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information,

necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our results of operations, financial performance and business.

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

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act or collectively, the CCPA, requires covered businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have been enacted in other states reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore, the Federal Trade Commission, or FTC, and many State Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, we may be subject to the European Union General Data Protection Regulation ("EU GDPR") and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR") (the EU GDPR and UK GDPR together referred to as the "GDPR"). The GDPR imposes strict requirements for processing the personal data of individuals within the European Economic Area, or EEA or UK, or in the context of our activities within the EEA and the UK. 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 / £17.5 million or 4% of the annual global revenues of the noncompliant undertaking, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the EU states that reliance on the standard contractual clauses, or SCCs - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis.

We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data

between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

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

Our business may be affected by the evolving regulatory framework for AI Technologies.

We use AI and machine learning (collectively, "AI Technologies") throughout our business, and are making modest investments in this area. The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

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

We may from time to time acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses, investments in complementary businesses, dispose of assets, or pursue other strategic alternatives. We have not made any acquisitions to date, and our ability to do so successfully is unproven. On September 30, 2024, we completed the sale of our VOWST Business to SPN, which included all inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of VOWST. 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 or disposed assets or businesses;
- additional exposure to cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure;
- difficulties retaining or integrating acquired personnel, technologies and operations;
- diversion of management time and focus from operating our business to transaction, acquisition integration, or disposition-related 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 or disposed 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, disposition, or any other transaction or strategic alternative may not materialize. Future acquisitions, dispositions, or alternatives could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, and may not achieve their intended benefits, any of which could harm our financial condition and our business. We cannot predict the number, timing or size of any transactions, or the effect that any such transactions might have on our operating results, our business, or our financial condition.

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

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

We are subject to complex and changing laws and regulations, which exposes us to potential liabilities, increased costs and other adverse effects on our business.

We are subject to complex and changing laws, regulations, and executive orders, and compliance with these laws and regulations and executive orders is onerous and expensive. New and changing laws, regulations, and executive orders can adversely affect our business by increasing our costs, limiting the Company's ability to pursue or offer a product candidate or product, and requiring changes to our business. New and changing laws, regulations, and executive orders can also create uncertainty about how such laws and regulations will be interpreted and applied. Regulatory changes and other actions that materially adversely affect our business may be announced with little or no advance notice we may not be able to effectively mitigate all adverse impacts from such measures. Differing interpretations of such legal obligations can expose us to significant fines, government investigations, litigation and reputational harm. If we are found to have violated laws, regulations, or executive orders, it could materially adversely affect our business, reputation, results of operations and financial condition.

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

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

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

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

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

As of December 31, 2025, we had net operating loss carryforwards, or NOLs, of $616.4 million for federal income tax purposes and $597.8 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOLs subject to expiration begin to expire in various amounts in 2035. Our federal NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration, but may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020. Our state NOLs also begin to expire in various amounts in 2035. As of December 31, 2025, we also had federal and state research and development and other tax credit carryforwards of approximately $46.2 million and $10.0 million, respectively, net of uncertain tax position reserves, available to reduce future income tax liabilities, if any. Our federal and state tax credit carryforwards begin to expire in various amounts in 2031 and 2028, respectively. The federal research and development tax credit carryforwards include an orphan drug credit carryforward of $25.9 million. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income or income tax liabilities, respectively.

In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income and income taxes, respectively. For these purposes, an ownership change generally

occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5% of a corporation's stock exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have experienced ownership changes in the past, per a Section 382 study performed through December 31, 2024. We believe that none of our existing tax assets will expire unused as a result of the calculated limitations resulting from such ownership changes. However, we may have experienced additional ownership changes since December 31, 2024, and we may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we have undergone additional ownership changes, or if we undergo ownership changes in the future, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.

Risks Related to Our Common Stock

We have in the past and may again in the future receive a notice of the failure to satisfy a continued listing rule from Nasdaq.

In November 2024, we received written notice from Nasdaq notifying us that the bid price for our common stock had closed below the $1.00 Bid Price Requirement for continued inclusion on The Nasdaq Global Select Market. Though we regained compliance with the Bid Price Requirement in a timely manner, if in the future our common stock again closes below the $1.00 per share minimum bid price required by Nasdaq for 30 consecutive business days, we would again receive another notice of non-compliance with Nasdaq's listing standards and face the risk of delisting.

If, in the future, our common stock fails to meet the Bid Price Requirement and we have effected a reverse stock split within the prior one-year period, we will not be eligible for any compliance period to address the bid price deficiency and would be issued a delisting determination rather than be granted a compliance period. Under these circumstances, we could appeal the delisting determination to a Nasdaq hearing panel, during which time any suspension or delisting action will ordinarily be stayed. If we were eligible for a compliance period, there can also be no assurance that we would regain compliance with the Bid Price Requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, maintain compliance with the other Nasdaq listing requirements, or be successful in appealing any delisting determination.

If our common stock is delisted in the future, it is unlikely that we will be able to list our common stock on another national securities exchange on a timely basis or at all, and, as a result, we expect our securities would be quoted on an OTC market. If this were to occur, we and our stockholders could face significant material adverse consequences, including limited availability of market quotations and analyst coverage for our common stock, and reduced liquidity for the trading of our securities. Delisting also could result in, among other things, a loss of investor confidence or interest in strategic transactions or opportunities, us being subject to regulation in each state in which we offer our securities, and difficulty in recruiting and retaining personnel through equity incentive awards.

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

Our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 29% of our outstanding voting stock as of December 31, 2025. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

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

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have also registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

We are a "smaller reporting company" as defined under the rules promulgated under the Exchange Act. We will remain a smaller reporting company until the fiscal year following the determination that both (i) the value of our voting and non-voting

common shares held by non-affiliates is more than $250.0 million measured on the last business day of our second fiscal quarter and (ii) our annual revenues are more than $100.0 million during the most recently completed fiscal year and the value of our voting and non voting common shares held by non-affiliates is $700.0 million or more as measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, or supplemental financial information.

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

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

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because the Board 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. Among other things, these provisions include those establishing:

- a classified Board with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board;
- 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 to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our Board;
- the ability of our Board 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 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, the chief executive officer, the president or the Board, 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 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, any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

General Risk Factors

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

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

- our ability to develop, execute and realize the benefits of strategic plans including accessing capital through potential business development and/or achieving overall financing goals;
- our requirement for additional capital to fund our operations following the third quarter of 2026;
- our ability to realize the benefits of the Transaction with SPN;
- our continued compliance with stock exchange listing standards;
- the success of competitive products or technologies;
- actual or anticipated changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- the success of any potential future commercialization efforts;
- developments related to any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and may make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;

- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

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

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

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

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

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

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

There has been an increase in litigation related to corporate diversity, equity and inclusion programs. Relatedly, both advocates and opponents to certain environmental and social matters are increasingly resorting to a range of activism forms, including media campaigns, shareholder proposals, and litigation, to advance their perspectives. To the extent we are subject to such litigation, activism or pressure, we may be required to incur costs or it may otherwise adversely impact our business or reputation.

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

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

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

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

Key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel, and senior management;
- a security incident response plan that includes procedures for responding to cybersecurity incidents;
- a third-party risk management process for key service providers based on our assessment of their criticality to our operations and respective risk profile, suppliers, and vendors who have access to our critical systems and information; and
- cybersecurity insurance to cover us for costs and expenses we may incur due to a cybersecurity incident.

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

Cybersecurity Governance

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

The Audit Committee receives quarterly reports from our Vice President, Bioinformatics & Information Technology, or VP of IT, on our cybersecurity risks. In addition, our VP of IT updates the Audit Committee, where it deems appropriate, regarding any cybersecurity incidents it considers to be significant or potentially significant. The Audit Committee regularly reports to the full Board regarding its activities, including those related to cybersecurity.

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

Our management team and IT Group takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our IT environment.

Item 2. Properties

Research and Offices

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

Clinical Manufacturing

We currently conduct our manufacturing operations in our leased facilities in Cambridge, Massachusetts, where we conduct process development, scale-up activities, the manufacture of active components for our biotherapeutic candidates, and quality control testing. We believe our current laboratory facilities and contract relationships are sufficient to meet our current bioprocess development and manufacturing needs. Product candidates may be brought into the facilities for economies of operation, or may remain external with contract manufacturing organizations, depending on business dynamics and development needs.

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

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

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

Holders

As of March 1, 2026, there were approximately eleven holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

Recent Sales of Unregistered Securities

We did not make any sales of unregistered securities during the quarter ended December 31, 2025.

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, 2025.

Item 6. [Reserved]

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

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

A discussion regarding our financial condition and results of operations for the years ended December 31, 2025 and 2024, including a year-to-year comparison between 2025 and 2024, is presented below. For a full discussion of changes from the year ended December 31, 2024 to the year ended December 31, 2023, refer to Management's Discussion and Analysis of Financial Condition and Results of Operation in Part II, Item 7. of our Annual Report on Form 10-K for the year ended December 31, 2024 (filed with the SEC on March 13, 2025).

Overview

We are a clinical-stage company focused on improving patient outcomes in medically vulnerable populations through discovery and development of novel live biotherapeutic product, or LBP, candidates. We led the successful development and approval of VOWST, the first FDA-approved orally administered microbiome biotherapeutic and a Breakthrough Therapy designated drug, which was sold to Société des Produits Nestlé S.A., or SPN, and with certain of its affiliates, collectively, Nestlé Health Science, in September 2024. We have established field-leading capabilities and platforms that are powered by best-in-field human data sets to advance a portfolio of products that can uniquely address diseases by targeting host pathways that are modulated by microbes in the human body, and, in particular, diseases associated with mucosal barrier-immune interface targets. We believe clinical and nonclinical data across our programs support the development of LBPs to target the prevention and treatment of a broad swath of infections, and to treat inflammatory and immune, or I&I, diseases. Our pipeline consists of SER-155, SER-603, and SER-147, as well as other potential candidates in earlier development.

Our LBP candidates are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. We maintain a differentiated live biotherapeutics drug discovery and development platform that includes good manufacturing practices, or GMP, manufacturing capabilities for this novel drug modality. Our pipeline assets, including SER-155 and SER-603, are designed to target multiple disease-relevant pathways and are manufactured from standard clonal cell banks via cultivation. Our knowledge base and platforms enable selection of bacteria for precision consortia design to drive specific clinical outcomes and further provide unique insights on microbe-associated disease targets. We are designing LBP candidates to modulate host function to increase epithelium integrity and to induce immune homeostasis and tolerance, as well as to prevent the colonization and overgrowth of pathogens in the gastrointestinal, or GI, tract. We believe that the scientific and clinical data from the development of VOWST (our then product candidate SER-109 program) and the data from the SER-155 Phase 1b study (described below) validate our novel therapeutic approach in both infectious disease and I&I diseases. In the context of infection, we believe that our technology may be replicable across different bacterial pathogens with the potential to develop live biotherapeutics to protect a range of medically compromised patients at risk of antimicrobial resistance, or AMR, infections and bloodstream infections, or BSIs, that can result from a compromised epithelial barrier and that can be a major cause of mortality.

SER-155, our most advanced LBP candidate, is an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial BSIs, including those that can harbor antimicrobial resistance, as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HSCT. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HSCT, and in December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT. In our placebo-controlled Phase 1b study of SER-155 in allo-HSCT, SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post HSCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. Importantly, we observed clinical translation on the drug candidate's mechanisms of action, including improvements in epithelial integrity and immune homeostasis. Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HSCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with our CRO, and manufacturing of drug substance, we have paused additional investment in that program, preserving the optionality to efficiently restart the study, while continuing to seek funding for the Phase 2 study.

Our current strategy prioritizes advancing our programs that target I&I indications. We have meaningfully advanced over the past decade our scientific understanding of how microbes in the GI functionally modulate pathways at the mucosal barrier-immune interface that are associated with inflammatory and immune-related disease. The clinical data from our SER-155 Phase 1b study in allo-HSCT, along with our extensive preclinical and translational clinical data compiled over the past decade support and inform the advancement of our earlier stage programs targeting I&I diseases. We are evaluating SER-155 in immune checkpoint-related

enterocolitis, or irEC, and we are developing SER-603, broadly in inflammatory bowel disease, or IBD, including ulcerative colitis, or UC, and Crohn's disease. We believe that our LBPs could represent a non-immunosuppressive treatment option for I&I diseases that are linked to colitis and could broadly address immune therapy toxicities, both of which represent significant unmet medical needs and potential commercial opportunities. We are currently exploring potential collaborations related to those I&I disease programs.

We have been collaborating with Memorial Sloan Kettering Cancer Center for over a decade on the impact of the GI microbiome on immune related diseases and cancer; recently this long-standing collaboration included an investigator-sponsored trial, or IST, evaluating SER-155 in 15 participants with irEC. irEC is among the most frequent and severe immune-related adverse events, or irAEs, in recipients of immune checkpoint inhibitor, or ICI, therapy and can be observed in up to 50% of patients, with rates varying based on cancer drug and treatment regimen. ICIs can cause a wide range of irAEs with links to T cell biology and epithelial barrier inflammation, both of which are biological functions shown in our preclinical and clinical pharmacology data to be positively impacted by SER-155. We expect to report initial clinical results, including preliminary safety, efficacy, pharmacology, and exploratory biomarker data in the second quarter of 2026. We believe data from this IST could further support the potential for live biotherapeutics to address a significant unmet need among the large population of cancer patients receiving ICIs and may further support evaluation of our biotherapeutic approach in this setting.

SER-603 is a novel, LBP candidate optimized to address disruptions in the GI microbiome and to improve GI mucosal barrier integrity through the inhibition of inflammatory bacteria and associated metabolites, the promotion of epithelial barrier integrity to reduce the translocation of inflammatory molecules and barrier inflammation, and to induce immune homeostasis through non-immunosuppressive regulatory T cell, or T-reg, induction via T cell signaling. Our research on SER-603 has been primarily supported through a partnership with the Crohn’s and Colitis Foundation, or CCF. These efforts aim to (i) confirm the functional phenotype and inflammatory state of patient subpopulations observed in our prior ulcerative colitis, or UC, clinical trials, and (ii) prioritize inflammatory targets and evaluate the potential to utilize biomarker-based patient selection and stratification for future studies. Many IBD patients experience an efficacy ceiling due to non-response or poor durability of response to existing therapies, and further, most advanced therapies target downstream inflammatory and immune responses and are immunosuppressive leading to toxicities and limitations with respect to combination therapies. IBD is a heterogeneous disease with both disruptions in the GI microbiome and epithelial barrier compromise being important drivers of disease that are not addressed by existing IBD therapies.

We believe that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations to address barrier compromise and bloodstream and AMR infections beyond allo-HSCT, including autologous-HSCT patients, cancer patients with neutropenia, chimeric antigen receptors therapy, or CAR-T, recipients, individuals with chronic liver disease, or CLD, solid organ transplant recipients, as well as patients in the intensive care unit, or ICU, and long-term acute care facilities. We continue to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including CLD. Additionally, we are developing an oral liquid formulation based on SER-155 strains, for dosing in patients who cannot take oral capsules, such as intubated patients in the ICU, and other medically vulnerable patients at high risk of AMR infections, supported by a grant from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator). We continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational development platform to prioritize future drug targets and to identify opportunities for monotherapy treatment and in combination with existing therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deploy a reverse translational platform and knowledge base, which we call our MbTx Platform, for the discovery and development of live biotherapeutics, and maintain extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for live biotherapeutics; and a strain library and associated microbiological capabilities that spans broad biological and functional breadth. This platform and knowledge base are integrated through a proprietary knowledge graph and agentic artificial intelligence, enabling rapid identification of specific microbes, microbial genes, and microbial metabolites/peptides associated with disease and the design of therapeutic consortia of bacteria for specific pharmacological properties to restructure the gut microbiome and modulate functional pathways associated with disease. In addition, we own a valuable intellectual property estate related to the development and manufacture of live biotherapeutics.

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

Our product candidates are in early-stage clinical or preclinical development. Our ability 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 from operations was $94.0 million, $121.3 million, and $195.1 million for the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $972.4 million.

While we plan to focus our investment on advancing our early-stage live biotherapeutic candidates, starting with SER-603, in the near-term and, subject to receiving additional funding, progressing the development of SER-155 into a Phase 2 study, our expenses may increase in connection with these future activities. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—*We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.*"

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

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of collaborations with third parties, public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of factors such as the impacts of pandemics, increases in inflation rates, interest rates and tariffs. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. Our inability to raise capital or secure a partnership as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of December 31, 2025, we had cash and cash equivalents totaling $45.8 million. Based on our currently available cash resources, and considering our future operating plans, we anticipate that we will require additional funding following the third quarter of 2026. In accordance with applicable accounting standards, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within 12 months after the date of the issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In performing this analysis, we excluded certain elements of our operating plan that cannot be considered probable of occurring. Under the applicable accounting standards, any future transactions or equity issuances cannot be considered probable, as these events are outside our control. Accordingly, management has concluded that substantial doubt exists about our ability to continue as a going concern for 12 months from the date the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, are issued. See "Risk Factors— Risks Related to Our Financial Position and Need for Additional Capital —*We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern*."

On September 23, 2025, we announced that we implemented cost reduction actions, including decreasing our workforce by approximately 25%. During the year ended December 31, 2025, we incurred approximately $1.0 million in restructuring costs, primarily related to severance costs. These costs were paid out in the fourth quarter of 2025.

Immunology and Inflammation

Irritable Bowel Disease and Ulcerative Colitis

UC, a form of IBD, is a relapsing-remitting chronic inflammatory disorder affecting the mucosal surface of the colon, leading to episodes of bloody diarrhea, urgency and mucosal inflammation (Danese and Fiocchi, 2011), which generally begins in young adulthood and endures for life. The incidence of UC is rising worldwide, and the prevalence of the disease is highest in the United States, Canada, and Europe. In the United States alone, the prevalence of UC is estimated to be 378 per 100,000, or approximately 1.25 million Americans (Lewis et al., 2023). The severity, extent, and duration of disease are also risk factors for developing colon cancer, which occurs at a rate as high as 0.5-1.0% per year, an important complication given the young age at which the disease strikes. Patients with UC also experience increased risk of *Clostridioides difficile* infection, or CDI, and primary sclerosing cholangitis, compared to the general population (Dlalal & Allegretti, 2022).

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

Current IBD therapies primarily suppress immune responses rather than address upstream drivers of immune activation. Despite advances in biologics and small molecules, many patients fail to achieve durable remission, and a substantial subset experience incomplete response, loss of response over time, or safety limitations associated with chronic immunosuppression. Additionally, current therapeutic approaches in IBD do not address the potential role of microbiome functional disruptions in causing or aggravating disease in IBD. However, not all patients with IBD present with microbiome disruption; many patients with IBD demonstrate comparable taxonomic and functional microbiome diversity to healthy subjects (Lloyd-Price 2019). Similarly, pre-clinical models have shown that microbiomes from patients with IBD drive variable immune responses, with only a subset of microbiomes resulting in inflammation (Hart et al. 2017; Britton et al. 2019). These data suggest that the microbiome may play a role in a subset of subjects with IBD.

Data from our SER-287 Phase 2b study and the first cohort of subjects from our SER-301 Phase 1b study in patients with mild-to-moderate UC suggest that the pharmacodynamic effects observed for SER-287 and SER-301 were greater in a subset of patients. Based on these results, we continue to advance research and development activities supported by partnerships to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts in IBD, and to further optimize our live biotherapeutic lead candidates. In October 2023, we were awarded a $500,000 grant from the CCF to leverage our clinical results and biological mechanism insights to functionally characterize subpopulations and to define associated biomarkers for IBD patient selection and stratification of patients where the GI microbiome plays an active role in inflammation and could be modified to reduce colitis. Our preclinical studies conducted to date have recapitulated the patient subpopulation observations from the previously run trials and progressed associated biomarker delineation of the populations, as well as confirmed a microbiome-driven functional link to disease. These research efforts aim to prioritize inflammatory targets for future clinical trials and evaluate the potential to utilize biomarker-based patient selection and stratification for these future studies.

SER-603

SER-603 is an investigational live biotherapeutic designed to improve response rates and durability of remission in patients with IBD, including UC and Crohn's disease. SER-603 is being developed for use as either a stand-alone therapy in mild-to-moderate disease or as a mechanism-distinct adjunctive therapy in combination with biologics or small molecules in moderate-to-severe disease. The program leverages our prior clinical experience in UC, including learnings from SER-287 and SER-301, and incorporates biomarker-driven patient stratification and optimized microbiome conditioning strategies.

SER-603 is in preclinical development, with IND-enabling activities ongoing. The program is supported by translational analyses from prior clinical studies and by preclinical studies that have recapitulated microbiome-defined patient subpopulation observations. We continue to evaluate biomarker-based patient selection approaches and functional characterization strategies to inform future clinical development.

Emerging clinical and preclinical evidence suggests that microbiome functional disruption contributes to disease activity in a defined subset of IBD patients. Observational and translational data from our prior SER-287 Phase 2b study and SER-301 Phase 1b study indicate that pharmacodynamic responses were greater in microbiome-defined subpopulations. These findings, along with external data demonstrating heterogeneity in microbiome-associated inflammatory responses, support the development of targeted, biomarker-informed live biotherapeutic strategies. We have discovered more than fifty GI bacterial features linked to inflammatory outcomes and have nominated and validated microbe associated biomarkers that can predict a response to current advanced therapies for IBD. Leveraging these biomarkers and our integrated preclinical and clinical data sets, SER-603 is optimized to address epithelial barrier dysfunction and microbiome-driven inflammation without systemic immunosuppression.

Given the chronic nature of IBD and continued unmet need for safe, durable, and non-immunosuppressive treatment options, we believe SER-603 has the potential to address a substantial commercial opportunity. SER-603 targets multiple segments of the IBD market, including moderate-to-severe UC (approximately 300,000-400,000 patients in the United States) as combination therapy with current standards of care, moderate-to-severe Crohn's disease in combination therapy setting, and mild-to-moderate UC and Crohn's disease as potential monotherapy.

Immune checkpoint-related enterocolitis (irEC)

IrEC is among the most frequent and severe irAEs in recipients of immune checkpoint-inhibitor therapy and can be observed in up to 50% of patients with rates varying based on cancer drug and treatment regimen. Immune checkpoint inhibitors can cause a wide range of irAEs with links to T cell biology and epithelial barrier inflammation, both of which are biological functions shown in our preclinical and clinical pharmacology data to be positively impacted by SER-155. We believe that supportive data from this study could provide further support for the expansion of indications that may be well suited for our biotherapeutic approach.

Immune checkpoint inhibitors are a commonly used class of drugs that promote anti-tumor immune activity for cancer treatment. irEC represents a growing and underserved market driven by the rapid expansion of ICI use across oncology. Importantly, irEC shares substantial pathophysiologic overlap with inflammatory bowel disease (IBD), including epithelial barrier dysfunction, dysregulated mucosal immunity, and microbiome perturbation. This biological convergence enables clinical, regulatory, and commercial synergies between irEC and IBD development programs. With approximately 500,000 patients using ICI globally, approximately 50,000 to 100,000 are anticipated to experience clinically significant irEC. irEC rates vary, with rates highest in CTLA-4-based and combination therapies (~50%); grade 2+ irEC can lead to discontinuation of therapy, risking further cancer progression.

SER-155 in irEC

SER-155 is currently being evaluated as a first-in-class live biotherapeutic candidate for the treatment of Grade 2–3 immune checkpoint inhibitor-related enterocolitis (irEC) as a result of ICI therapy. The program is designed to promote mucosal healing and modulate inflammation without systemic immunosuppression, with the goal of reducing or eliminating the need for high-dose corticosteroids, which carry the risk of toxicity and ICI efficacy impact. We believe SER-155 could be a first-in-class therapy; current approaches manage toxicity reactively with immunosuppression, which can negatively impact cancer treatment.

We are nearing completion of a single-arm, open-label Phase 1b investigator-sponsored trial conducted with Memorial Sloan Kettering Cancer Center evaluating SER-155 as first-line treatment of irEC. The study was fully enrolled (n=15) in early 2026, and we expect to report initial clinical results, including preliminary safety, efficacy, pharmacology, and exploratory biomarker data in the second quarter of 2026.

Infection Risk Reduction

We continue to be invested in the infectious disease space, with a renewed focus on leveraging our existing clinical data, translational insights, and manufacturing capabilities to support targeted development efforts across a defined set of related indications. We believe that the scientific and clinical data from our VOWST program (our then product candidate SER-109 program) validate our novel approach of using live biotherapeutics to decolonize pathogens and improve epithelial barrier integrity, resulting in reduced rate of infections in medically compromised patients. Data from the ECOSPOR III and ECOSPOR IV Phase 3 trial published in the *New England Journal of Medicine* (Feuerstadt et al., 2022) and *Journal of the American Medical Association*(Sims et al., 2023) suggest that live biotherapeutics have the potential to restructure the gut microbiome and shift the gut metabolic landscape. Additional data show that VOWST rapidly reduced the abundance of bacteria associated with common antibiotic resistance genes, or ARGs, and reduced ARG abundance in the gut (Straub et al., 2023). Collectively, we believe these data suggest the potential for live biotherapeutics to prevent the colonization and overgrowth of pathogens that can establish in the gut and ultimately to reduce infections. We believe that reducing pathogen colonization in the GI and improving GI epithelial barrier integrity to reduce the risk of infection may be replicable in a range of medically compromised patients, protecting them from infections and resulting downstream clinical sequelae.

We believe this approach may also enable us to reduce AMR, which the World Health Organization declared as a top ten global public health threat facing humanity, and with estimates that yearly deaths may reach 10 million by 2050, putting mortality due to AMR on par with deaths due to cancer. Recently, two manuscripts were published in *Nature Medicine* (Bryant et al. 2026) and the *Journal of Infectious Diseases* (Bryant et al. 2025) highlighting new insights into the functional mechanism and clinical impact of VOWST. The *Nature Medicine article*, titled "The impact of an oral purified microbiome therapeutic on the GI microbiome", confirmed our pharmacological hypotheses from earlier VOWST studies, with higher VOWST dosing associated with enhanced pharmacokinetics, as assessed by faster and more robust therapeutic species engraftment in the gut. Treatment also significantly altered the composition of the intestinal microbiome and microbe-associated metabolites, including decreased primary and increased secondary bile acids, as well as elevated short- and medium-chain fatty acids, functional changes that inhibit C. difficile spore germination and vegetative growth. Further, in vitro analyses confirmed that VOWST batches induced production of these metabolites that disrupt C. difficile life cycle and growth. Collectively, these findings support VOWST's role in restoring microbe-associated metabolic functions critical to preventing CDI recurrence. A complementary publication in the *Journal of Infectious Diseases*, titled "Comparability of Gastrointestinal Microbiome and Bile Acid Profiles in Patients With First or Multiply Recurrent Clostridioides difficile Infection", reported a post hoc analysis of the ECOSPOR IV Phase 3 trial, evaluating differences in gastrointestinal microbiome and bile acid profiles between patients experiencing a first recurrence C. difficile infection (frCDI) versus multiply recurrence infection (mrCDI). These data demonstrate that the underlying functional disease etiology is consistent in both first and multiply recurrent CDI patient populations, with VOWST demonstrating similar efficacy and drug pharmacology across the broad patient population.

We believe these data provide important clinical translation and further demonstrate the potential of live biotherapeutics to target specific microbiome functions that are linked to serious disease, including those that are not effectively treated with other drug modalities. The underlying data supporting these publications was developed using Seres MbTx platform, which provides high-resolution assessment of drug pharmacology and functional mechanism of action. These data on bacterial function and pharmacology anchored the preclinical development of SER-155 and inform the continued development of Seres' pipeline of next-generation live biotherapeutic products.

SER-155 in allo-HSCT

We are developing SER-155, an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial BSIs as well as other pathogen associated negative clinical outcomes in patients undergoing allo-HSCT. SER-155 is a live biotherapeutic candidate designed to prevent frequent, expensive, and fatal infections in blood cancer patients.

SER-155 contains 16 bacterial strains selected using our reverse translation discovery and development platform technologies to optimize SER-155's targeted profile. The design incorporates biomarker data from human clinical data and screening data from nonclinical human cell-based assays and in vivo disease models. The bacteria consortia is designed to optimize: (i) the prevention of the growth of various *Enterococcaceae* and *Enterobacteriaceae* species known to potentially dominate the GI tract and lead to downstream negative clinical outcomes in medically compromised patients and that can harbor antibacterial resistance, (ii) the production of multiple bacterial metabolites that can promote mucosal and epithelial barrier integrity with the goal of reducing the likelihood of harmful bacteria translocating from the gut to the bloodstream through a compromised epithelium, and (iii) the

production of multiple bacterial metabolites that can modulate immune pathways to induce immune tolerance with a potential impact on GvHD.

The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan Kettering Cancer Center showing that allo-HSCT patients with decreased diversity of commensal microbes and pathogen domination in the GI tract were significantly more likely to die due to infection and/or lethal GvHD (Peled et al., 2020). There are an estimated 40,000 allo-HSCT procedures annually worldwide, and infection is one of the most common causes of mortality in these patients. The Center for International Blood & Marrow Transplant Research, or CIBMTR, reports that 19-28% of deaths in allo-HSCT patients over 18 years of age within 100 days post-transplant are caused by infections and 5-14% by GvHD. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in allo-HSCT patients. In December 2024, the FDA granted Breakthrough Therapy designation for SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HSCT.

SER-155 Phase 1b Study (including placebo-controlled Cohort)

SER-155 has been evaluated in a Phase 1b study in patients undergoing allo-HSCT. The SER-155 Phase 1b study included two cohorts. Cohort 1 was designed to assess safety and drug pharmacology, specifically the drug strain engraftment in the GI tract. Cohort 1 included 13 subjects who received any dosing of the SER-155 regimen, with 11 subjects subsequently receiving an allo-HSCT. Results from this cohort, announced in May 2023, showed SER-155 was generally well tolerated and resulted in successful drug strain engraftment and a reduction in pathogen domination in the GI microbiome relative to a historical control cohort.

Study Cohort 2 utilized a randomized, double-blinded 1:1 placebo-controlled design to further evaluate safety and drug strain engraftment, as well as key secondary and exploratory endpoints such as the incidence of bacterial bloodstream infections and related medical consequences such as febrile neutropenia and antibiotic use. Cohort 2 included 45 patients in the intention-to-treat (ITT) population. Of the ITT population, 20 received SER-155 and 14 received placebo, each of whom subsequently received an allo-HSCT, with data available for clinical evaluation through day 100, the study's prespecified primary observation point. Exploratory hypothesis testing was conducted at the two-sided α=0.05 level. Ninety-five percent (95%) 2-sided confidence intervals (CIs) were determined, where specified. No adjustment for multiplicity was done. A subset of patient samples was available for drug pharmacology analysis.

The median age in Cohort 2 was 63, and most subjects had acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome or myeloproliferative neoplasia as their primary disease and received reduced-intensity conditioning pre-transplant. Most patients received peripheral blood stem cells from a matched unrelated donor. A majority received post-transplant cyclophosphamide as part of their GvHD prophylaxis.

Results from Cohort 2, announced in September 2024, were consistent with the observations from Cohort 1. SER-155 was generally well tolerated, and no treatment-emergent serious adverse events related to drug were observed. SER-155 bacterial strains engrafted into the gastrointestinal tract of patients following the administration of SER-155.

The incidence of BSIs was significantly lower in the SER-155 arm compared with the placebo arm (2/20 (10%) vs. 6/14 (42.9%), respectively; [Odds Ratio: 0.15; 95% CI: 0.01, 1.13, p=0.0423]), which represents a relative risk reduction of approximately 77% and an absolute risk reduction of approximately 33%. In addition, while treatment antibiotic starts were similar in each arm, patients administered SER-155 were treated with antibiotics for a significantly shorter cumulative duration compared to patients in the placebo arm (9.2 days vs. 21.1 days, respectively, with a mean difference of -11.9 days [95% CI: -23.85, -0.04; p=0.0494]). The incidence of febrile neutropenia was lower in patients administered SER-155 compared to placebo (65% vs. 78.6%, respectively; [Odds Ratio: 0.51; 95% CI: 0.07, 2.99; p=0.4674]). Six cases of GI infections (C. difficile infections) were observed in the study, with four cases (20%) in the SER-155 arm and two cases (14.3%) in the placebo arm.

Recent changes in the allo-HSCT standard of care and the increasing use of post-transplant cyclophosphamide as part of prophylactic therapy for GvHD have reduced rates of GvHD overall in this patient population. The rates of GvHD in the study were low, with two cases of grade 2 GvHD observed in each arm, and no cases of grade 3 or 4 GvHD were observed.

In Cohort 2, the ability to detect pathogen domination (i.e., relative abundance in the GI $\geq$30%) in the placebo arm, and differences between the study arms, was constrained due to the limited number of placebo stool samples and an imbalance in the number of available stool samples between the arms. Observed pathogen domination events were low in the placebo and SER-155 arms with no significant differences identified. In a comparison of the prevalence of pathogen domination versus a larger allo-HSCT historical control cohort, pathogen domination in SER-155 subjects was substantially lower, providing further evidence of SER-155 activity.

We believe the available study data from Cohort 1 suggest that SER-155 administration results has the potential to significantly lower incidence rates of gastrointestinal dominations with pathogens of clinical concern, such as *Enterococcaceae*, *Enterobacteriaceae*, *Streptococcaceae*, and *Staphylococcaceae*. We further believe the resulting Cohort 2 data, together with the Cohort 1 SER-155 Phase 1b study results provide encouraging evidence to support further development of SER-155 to potentially reduce GI associated bloodstream and AMR infections as well as increase immune tolerance in individuals undergoing allo-HSCT for cancers and other serious conditions.

Proposed SER-155 Phase 2 Study

The SER-155 Phase 2 study will incorporate a well-powered, placebo-controlled design, which provides for a planned interim analysis to enable an expedited initial data readout. The SER-155 Phase 2 study is expected to enroll approximately 248 participants and incorporate an adaptive design and an interim data analysis when approximately half of the enrolled participants have reached the primary endpoint. We expect to obtain the interim clinical results within twelve months following study initiation, which we believe will facilitate timely engagement with the FDA on the design of a Phase 3 study and inform development in adjacent medically vulnerable patient populations. We believe that positive results, if achieved, from the Phase 2 study could enable advancement into a single Phase 3 trial to support registration.

Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HSCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with our CRO, and manufacturing of drug substance, we have paused additional investment in that program while continuing to seek funding for the Phase 2 study.

We continue our efforts to obtain capital and other resources to support further development of SER-155 and our broader portfolio of live biotherapeutic product candidates with applications for inflammatory diseases. We are evaluating a range of potential deal structures that we believe could leverage our live biotherapeutics expertise and success, as demonstrated by bringing VOWST from early development through FDA approval.

In October 2025, we presented new post hoc data from our SER-155 Phase 1b trial in an oral presentation at IDWeek in Atlanta, Georgia. The presentation included new post-hoc analysis from the completed SER-155 Phase 1b study describing differences between the SER-155 and placebo groups, including the bacterial and fungal organisms causing BSIs, BSI event clinical outcomes, antibacterial prophylaxis use, and patterns of AMR among the bacterial BSI organisms. These new data illustrated that BSIs occurred despite antibacterial prophylaxis, and that BSI bacteria exhibited AMR. Resistance to multiple antibacterial agent classes was observed only in the BSI bacteria from placebo-treated participants, two of whom had fatal outcomes related to their BSIs. These new data further support the potential of SER-155 as an innovative alternative approach to the significant unmet medical need for prevention of BSIs in HSCT patients, especially those BSIs associated with AMR that increases the risk of morbidity and mortality.

Exploratory biomarker data

In January 2025, we reported exploratory translational biomarker data from the SER-155 Phase 1b study which provided evidence supporting the intended therapeutic mechanisms, including promotion of intestinal epithelial barrier integrity to reduce the potential of bacterial translocation into the bloodstream, and reduction of systemic inflammatory responses. Results from this exploratory biomarker analysis showed that SER-155 was associated with lower levels of fecal albumin and lower concentrations of various plasma biomarkers associated with systemic inflammation (i.e., IFN-y, TNF-α, IL-17, and IL-8) in the HSCT peri-transplant period, the period from the end of the first SER-155 treatment course through to neutrophil engraftment. The results support SER-155's intended mechanisms of action and reinforce the previously reported promising clinical study efficacy and safety data. These systemic inflammatory response observations further support the potential to develop our live biotherapeutics to address inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

In February 2025, clinical and biomarker results from our biotherapeutic programs were presented as a poster at the 2025 Tandem Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and Center for International Blood and Marrow Transplant Research (CIBMTR). SER-155 Phase 1b clinical study data were also featured in an oral presentation in the Best Abstracts in Infectious Diseases track at the Tandem meeting.

In April 2025, we presented SER-155 Phase 1b clinical and exploratory biomarker results at the 51st annual meeting of the European Society for Blood and Marrow Transplantation, or EBMT. Our presented poster was recognized by the EBMT scientific organizing committee and obtained the "Best Clinical Poster Award."

In May 2025, we presented data at the Digestive Disease Week, or DDW conference highlighting preclinical and clinical data that enable identification of patients with a disease etiology linked to the gastrointestinal microbiome, and the identification of microbiome-based biomarkers that are predictive of response and suitable for patient selection and stratification in clinical trials. Our poster, entitled "Candidate Biomarkers of Microbiome Disruption for Patient Selection or Stratification in Clinical Trials of Microbiome Therapies in Ulcerative Colitis" received a Poster of Distinction award in the Microbiome and Microbial Therapies subgroup. We believe that the data generated suggest that live biotherapeutics could provide a novel treatment modality that could benefit patients living with gut-related inflammatory and immune diseases that are not effectively addressed today. Furthermore, research indicates that specific patient subpopulations optimally suited for biotherapeutic-based treatments may be identifiable. We are exploring options, including potential partnerships, to advance the development of our biotherapeutics in inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

In May 2025, we presented new exploratory biomarker data from the SER-155 Phase 1b study in a poster session at the 2025 American Society of Clinical Oncology, or ASCO, Annual Meeting. The biomarker data presented at ASCO demonstrate the potential of SER-155 to promote immune reconstitution following allo-HSCT by modulating homeostatic cytokines and peripheral T-cell expansion. In post hoc analyses from the SER-155 Phase 1b study, significantly higher levels of the homeostatic cytokine IL-7 were

observed both after the second course of SER-155 (administered after neutrophil recovery) and at HSCT Day 100, as compared to placebo. Additionally, a higher frequency of CD4+ T cells was observed in peripheral blood at these same timepoints in the SER-155 arm. We believe the results support the ability of SER-155 to promote peripheral T-cell recovery and immune reconstitution to support favorable outcomes post allo-HSCT.

We believe that exploratory biomarker data presented at recent medical meetings have supported the intended mechanisms of SER-155 and demonstrated the broader potential of live biotherapeutics in inflammatory and immune mediated diseases.

Oral Live Biotherapeutic Product - Liquid Formulation (LBP-LF)

In July 2025, we were awarded a grant from CARB-X to support the development of an oral liquid formulation of an LBP based on SER-155 (LBP-LF) for medically vulnerable patient populations at risk of BSIs, including AMR infections, who cannot be dosed with oral capsules, such as intubated patients in the ICU. The CARB-X grant provides us with up to $3.6 million of funding for research, manufacture, and design of a Phase 1 clinical trial in ICU patients. LBP-LF is designed to target the prevention of bloodstream infections in medical ICU patients by *Escherichia coli* and other gut-derived bacteria capable of harboring antibiotic resistance. Up to 50% of all preventable medical ICU deaths have been attributed to infections with *E. coli* and other gut-derived bacteria (Mayr, 2006). These infections are also the leading cost in the medical ICU (Neidell, 2012). When ICU patients with multidrug resistant, or MDR, infections survive hospitalization, they have high long-term morbidity with over 20% 30-day readmission rates (Chang, 2015; Mayr, 2017). Over 5 million patients are admitted to ICUs in the U.S. annually, and these admissions account for approximately 20% of all acute care hospitalizations (Barrett et al. 2024).

Infections with pathogenic, often MDR, bacteria are the leading cause of mortality in the medical ICU, causing up to 9 deaths for every 100 ICU patients admitted (Vincent, 2009). Most patients are admitted to the medical ICU with a known or suspected infection (i.e., sepsis) but, with targeted or empiric antibiotics, most recover from this initial infection. Once in the ICU, secondary, healthcare-associated infections frequently develop during the prolonged recovery from sepsis and are a significant driver of mortality. LBP-LF is a novel approach that addresses both gut colonization and subsequent translocation by *E. coli* and other gut-derived pathogens to prevent a significant proportion of these secondary hospital acquired infections. LBP-LF is in preclinical development, with IND-enabling activities ongoing and IND-readiness targeted by the end of 2026. Development of LBP-LF is ongoing with grant support from CARB-X and in collaboration with Columbia University.

SER-147

We are also developing another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including chronic liver disease, or CLD. SER-147 was designed and optimized using our reverse translational therapeutics development platform. CLD is a progressive condition marked by deterioration of liver function and is reaching epidemic proportions affecting nearly 1.7 billion people worldwide, causing substantial health burden on afflicted countries (GBD 2017 Cirrhosis Collaborators, 2020, Clinical Liver Disease, 2021).

In the advanced stages of CLD, known as decompensated cirrhosis, patients exhibit significant immune dysfunction, microbiome disruption, and increased contact with the healthcare system, all of which drive increased susceptibility to bacterial infections such as SBP and BSIs (Bajaj et al., 2021, Albillos et al., 2022). Over 40% of patients with decompensated cirrhosis experience an infection within the first year of diagnosis. Antibiotics are the only prophylactic option for patients at high risk of infections like SBP, resulting in exposure to antibiotics for months or years. To combat increasing rates of AMR, antibacterial prophylaxis for primary SBP is no longer recommended for the majority of patients outside of very high-risk, leaving significant unmet need. Many cultivated live biotherapeutics currently in clinic are constrained by formulation technologies incompatible with concomitant medications commonly used in CLD.

SER-147 is in preclinical development. The program is ready to progress to IND-enabling activities, including manufacturing, in order to advance to clinical development.

Nasdaq Notice and Compliance

On November 7, 2024, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the $1.00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1), or the Bid Price Requirement.

On April 21, 2025, we effected a 1-for-20 reverse stock split of our common stock. Trading of our common stock on The Nasdaq Global Select Market commenced on a split-adjusted basis on April 22, 2025 and we regained compliance with the Bid Price Requirement.

All shares of our common stock, stock-based instruments, and per-share data included in this Annual Report on Form 10-K have been retroactively adjusted as though the reverse stock split had been effected prior to all periods presented.

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. 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-155 and SER-147 extend through 2043 (not including any potential term extension). We plan on continuing to broaden our patent portfolio. Currently, we have 22 active patent families, which includes 18 nationalized applications and three at the provisional stage. To date, we have obtained issuance of 33 U.S. patents (which includes three as licensee). Of the issued U.S. patents, 13 U.S. patents (including one as licensee) have been assigned to Nestlé Health Science as part of its purchase of VOWST.

In connection with the Transaction and pursuant to the Purchase Agreement, we transferred certain patents and trademarks affiliated with the VOWST Business to SPN at Closing. In addition, in connection with Closing, we entered into a cross-license agreement, or the Cross-License Agreement, with SPN. Under the Cross-License Agreement, we granted to SPN a perpetual, worldwide, non-exclusive, fully paid-up license under certain Seres patents that have been issued or will issue in the future and current know-how controlled by us that was not transferred to SPN pursuant to the Purchase Agreement. In the field of the treatment of CDI and recurrent CDI and associated complications, or collectively, the CDI Field, the license to SPN under such Seres patents and know-how is exclusive to SPN for five years after the Closing and co-exclusive between SPN and Seres following that five year period. The license from Seres to SPN is to issued Company patents that currently or in the future cover the Product or improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the VOWST Business. We also granted SPN an exclusive, perpetual, worldwide, fully paid-up license under issued Seres patents that currently or in the future cover the Product and improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the Product to exploit SER-262 in the CDI Field. SPN granted to us a perpetual, worldwide, non-exclusive license under the patents and know-how that are transferred to SPN pursuant to the Purchase Agreement or developed under the TSA, for Seres' products for use outside of the CDI Field, and after five years from Closing for Seres products containing designed, cultivated, bacterial consortia not manufactured using human stool (excluding SER-262) in the CDI Field. From and after Closing, certain license agreements between us, SPN, and/or their respective affiliates terminated and are of no further force or effect, except as contemplated by the Purchase Agreement.

Regulatory Exclusivity

If we obtain marketing approval for any of our product candidates, we expect to receive reference product exclusivity against biosimilar products.

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. In connection with the TSA we entered into with NESA following the sale of the VOWST Business during the third quarter of 2024, our operating expenses also consisted of certain passthrough costs incurred in performing duties under the TSA and manufacturing services related to the VOWST Business and operations.

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 and other obligations, 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 and other third parties that manufacture or test 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;

- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs; and
- labor and passthrough costs, reimbursable by Nestlé, incurred in performing duties under the TSA.

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

Our primary focus of research and development since inception has been on our reverse translational platform and the subsequent development of our product candidates. Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to investigators, consultants, CROs in connection with our preclinical studies and clinical trials, lab supplies and consumables, and regulatory fees. We do not allocate employee-related costs and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under development.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We anticipate an overall decrease in research and development expenses in 2026 as compared to 2025, following the conclusion of the TSA, completion of the Phase 1b study of SER-155 in allo-HSCT, and the cost reduction actions that were implemented in September 2025 and February 2026, including pausing investment in the SER-155 Phase 2 study and headcount reductions. Research and development expenses may increase in the future if and as we resume development of any clinical or preclinical programs. In 2025, research and development expenses included labor and passthrough costs, reimbursable by Nestlé, incurred in performing obligations under the TSA. Given the conclusion of the TSA as of December 31, 2025, these costs and related reimbursements are not expected to reoccur in 2026.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation for personnel in our executive, finance, commercial, business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs. In 2025, general and administrative expenses included labor and passthrough costs, reimbursed by Nestlé, incurred in performing obligations under the TSA.

We expect that our general and administrative expenses will decrease in 2026 as compared to 2025, following the conclusion of the TSA, reduction of our workforce and overall cost containment efforts. General and administrative expenses may increase in the future as we continue to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing rules and the requirements of the SEC, director and officer insurance costs and investor and public relations costs.

Manufacturing Services

Under the TSA with NESA, beginning in the fourth quarter of 2024, we provided certain manufacturing services and related functions of the VOWST Business and operations. Expenses associated with the manufacturing services include certain facility-related, labor, lab supplies and consumables, and other manufacturing costs that would have been capitalized into inventory prior to the sale of VOWST Business.

We provided the manufacturing services until December 31, 2025. We do not expect to incur any expenses related to manufacturing services related to the VOWST business in the future, as the TSA and other Transaction-related obligations concluded on December 31, 2025.

Other (Expense) Income, Net

Interest Income

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

Interest Expense

Interest expense consists of interest incurred under our loan and security agreement, or the Hercules Loan and Security Agreement, with Hercules Capital, Inc., or Hercules.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of:

- sublease income;
- amortization of premiums or accretion of discounts on investments;
- gains and losses on foreign currency transactions;
- changes in the fair values of our warrant liabilities associated with our prior credit facility with Oaktree;
- loss associated with the extinguishment of our prior credit facility with Oaktree;
- the amount Nestlé paid for costs associated with PRMS manufacturing; and reimbursement for certain labor and other passthrough costs of the transition services performed by the Company under the TSA; and
- gains or losses associated with the change in the Company's accrued liabilities due to SPN - related party.

Discontinued Operations

We completed the sale of the VOWST Business to SPN on September 30, 2024. The financial results of the VOWST Business have been classified as discontinued operations in the consolidated statements of operations and the related assets and liabilities of the VOWST Business have been classified as assets and liabilities of discontinued operations in the consolidated balance sheets. Unless otherwise noted, amounts and disclosures in this section relate to our continuing operations (except for the Liquidity and Capital Resources section).

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, 2025, we had federal and state NOL carryforwards of $616.4 million and $597.8 million, respectively, both of which begin to expire in 2035. As of December 31, 2025, we also had federal and state research and development tax credit carryforwards of $46.2 million and $10.0 million, respectively, net of uncertain tax position reserves, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of $25.9 million.

Critical Accounting Policies and Significant Judgments and Estimates

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

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 advance payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time, which include information from our CROs and CMOs reported to us on a periodic basis. Examples of estimated accrued research and development expenses include fees paid to:

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

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024.

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Revenue:			
Grant revenue	789	—	789
Total revenue	789	—	789
Operating expenses:			
Research and development expenses	49,060	64,600	(15,540)
General and administrative expenses	39,156	53,183	(14,027)
Manufacturing services	6,544	3,532	3,012
Total operating expenses	94,760	121,315	(26,555)
Loss from operations	(93,971)	(121,315)	27,344
Other income:			
Gain on sale of VOWST Business	80,685	5,684	75,001
Interest income	2,227	3,967	(1,740)
Other income (expense), net	16,755	(14,107)	30,862
Total other income (expense), net	99,667	(4,456)	104,123
Net income (loss) from continuing operations	$ 5,696	$ (125,771)	$ 131,467

Revenue

Total revenue was $0.8 million for the year ended December 31, 2025 consisting of costs reimbursable under the CARB-X grant that we were awarded in the third quarter of 2025.

Research and Development Expenses

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Live biotherapeutics platform	$ 23,573	$ 29,006	$ (5,433)
SER-155	3,687	6,804	(3,117)
Early stage programs	247	101	146
Total direct research and development expenses	27,507	35,911	(8,404)
Personnel-related (including stock-based compensation)	21,553	28,689	(7,136)
Total research and development expenses	$ 49,060	$ 64,600	$ (15,540)

Research and development expenses were $49.1 million for the year ended December 31, 2025, compared to $64.6 million for the year ended December 31, 2024. The decrease of $15.5 million was due primarily to the following:

- a decrease in personnel-related costs of $7.1 million, primarily due to a decrease in salaries, bonuses, employee benefits expenses, and stock-based compensation expense due to lower headcount,
- a decrease of $5.4 million in expenses related to our live biotherapeutics platforms and research and development operations comprised of a decrease of $3.3 million of facilities and depreciation expense primarily due to the impairment charge that we recorded in the first quarter of 2024 related to our idled donor collection facility in Cambridge, Massachusetts, as well as decreases of $0.7 million of consulting and other costs, $0.6 million of clinical storage costs, and $0.8 million of lab assays; and
- a decrease of $3.1 million in expenses related to our SER-155 program due to lower clinical trial costs of $3.7 million as the Phase 1b study has been completed, partially offset by an increase of $0.3 million in lab supplies and consumables due to the commencement of manufacturing of clinical trial material for the planned Phase 2 study and an increase of $0.3 million of regulatory consulting.

General and Administrative Expenses

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Personnel-related (including stock-based compensation)	$ 14,413	$ 22,679	$ (8,266)
Professional fees	8,991	9,805	(814)
Facility-related and other	15,752	20,699	(4,947)
Total general and administrative expenses	$ 39,156	$ 53,183	$ (14,027)

General and administrative expenses were $39.2 million for the year ended December 31, 2025, compared to $53.2 million for the year ended December 31, 2024. The decrease of $14.0 million was primarily due to the following:

- a decrease in personnel-related costs of $8.3 million primarily due to a decrease in salaries, bonus, employee benefit expenses and stock-based compensation expenses due to lower headcount;
- a decrease in professional fees of $0.8 million primarily due to a decrease of $1.1 million related to lower audit, tax, and other consulting services, partially offset by a $0.3 million increase in legal fees; and
- a decrease in facility-related and other costs of $4.9 million primarily related to headcount-based information technology costs that were reduced as a result of lower headcount, as well as impairment charges recorded in the first quarter of 2024.

Manufacturing Services

Manufacturing services were $6.5 million for the year ended December 31, 2025, compared to $3.5 million for the year ended December 31, 2024. The TSA with Nestlé was effective in the fourth quarter of 2024, while 2025 reflects a full year of manufacturing services. The expenses are associated with the PRMS manufacturing performed on behalf of Nestlé, including labor, materials, allocated facility-related, lab supplies and other manufacturing costs that would have been capitalized into inventory prior to the sale of VOWST Business.

Other Income (Expense), Net

Other income (expense), net was $99.7 million of income for the year ended December 31, 2025 compared to $4.5 million of expense for the year ended December 31, 2024. The change in other income (expense), net was primarily due to the $75.0 million of installment payments received from Nestlé in January and July 2025, which were conditioned on our material compliance with obligations under the TSA, an increase of $7.0 million of reimbursement income from Nestlé associated with the performance of TSA services, and $0.6 million increase in sublease income. The increases were partially offset by a decrease in interest income of $1.7 million due to our lower cash balance. Additionally, the year ended December 31, 2024 included a $23.4 million loss associated with the extinguishment of the prior credit facility with Oaktree recorded in connection with the sale of the VOWST Business to SPN.

Liquidity and Capital Resources

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

On August 5, 2024, we entered into the Purchase Agreement with SPN, pursuant to which we agreed to sell our VOWST Business to SPN and its designated affiliates, and SPN and its designated affiliates assumed certain liabilities from us. The Transaction closed on September 30, 2024 following stockholder approval. As consideration for the Transaction, SPN agreed to pay us:

(i) a cash payment, which was paid at Closing, of $100 million, less approximately $17.9 million owed by us to an affiliate of SPN as of March 31, 2024 under the prior license agreement between us and the SPN affiliate, less approximately CHF 2.0 million in satisfaction of fees due under an existing manufacturing agreement between us and Bacthera;

(ii) cash installment payments of $50 million, which was received on January 15, 2025 and $25 million, which was received on July 1, 2025, (offset by $1.4 million paid by us to Nestlé on July 1, 2025 related to certain employment obligations assumed by SPN, as described below), conditioned on our material compliance with obligations under the TSA entered into at Closing between us and NESA;

(iii) prepayment of the $60 million Prepaid Milestone tied to the achievement of the First Sales Milestone of worldwide annual net sales of the Product of $150 million, which was paid in cash at Closing, which Prepaid Milestone will accrue interest at a fixed rate of 10% per annum until the First Sales Milestone is achieved and 5% per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set-off and (y) the last day of the Milestone Period; and

(iv) future Milestone Payments of (x) $125 million tied to the achievement of worldwide annual net sales of the Product of $400 million and (y) $150 million tied to the achievement of worldwide annual net sales of the Product of $750 million, during the Milestone Period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs.

As they are earned, the Milestone Payments will be satisfied as follows: (i) first, by set-off against all accrued interest on the Prepaid Milestone until the amount of such accrued interest has been paid in full, (ii) second, by set-off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (iii) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period (defined below), the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set-off of SPN with respect thereto will be deemed forfeited. The installment payment received on July 1, 2025 was offset by the $1.4 million we paid to Nestlé on the same date related to certain employment obligations assumed by SPN through the period prior to the Closing Date.

As a condition to Closing, we and SPN entered into the Securities Purchase Agreement, pursuant to which SPN purchased 714,285 shares of Common Stock at Closing, at a purchase price per share of $21.00, for an aggregate purchase price of $15.0 million.

In May 2021, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock with aggregate gross sales proceeds of up to $150.0 million, from time to time, through an "at-the-market" equity offering program under which Cowen acts as sales agent. During the year ended December 31, 2025, we sold 739,545 shares of common stock under the Sales Agreement, at an average price of approximately $18.48 per share, raising aggregate net proceeds of approximately $13.2 million after deducting an aggregate commission of approximately 3%. During the year ended December 31, 2024, we sold 1,030,846 shares of common stock under the Sales Agreement, at an average price of approximately $23.67 per share, raising aggregate net proceeds of approximately $23.5 million after deducting an aggregate commission of approximately 3% and other issuance costs.

As of December 31, 2025, we had cash and cash equivalents totaling $45.8 million and an accumulated deficit of $972.4 million. For the year ended December 31, 2025, we incurred a net loss from operations of $94.0 million, and used cash in operations of $73.9 million, net of $75.0 million in milestone payments received from Nestlé. We expect that our operating losses and negative cash flows will continue for the foreseeable future.

Under applicable accounting standards, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the consolidated financial statements are issued. The ability to obtain sufficient proceeds from additional equity offerings, collaborations or other financing with terms favorable or acceptable to us cannot be considered probable, as these events are outside of our control. Based on our currently available cash resources, and considering our future operating plans, we anticipate that we will require additional funding following the third quarter of 2026. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing or enter into a partnership. If potential collaborators or partners decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. We will need to generate significant revenues to achieve profitability, and we may never do so. Because of the numerous risks and uncertainties associated with the development of our current and any future product candidates, the development of our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are

unable to estimate the amounts of increased capital outlays and operating expenses required for completing the research and development of our product candidates.

Cash Flows

The following table summarizes our sources and uses of cash, cash equivalents and restricted cash for the years ended December 31, 2025 and 2024.

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Cash provided by (used in) operating activities	$ 1,117	$ (148,609)
Cash (used in) provided by investing activities	$ (42)	$ 142,293
Cash provided by (used in) financing activities	$ 13,898	$ (90,372)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 14,973	$ (96,688)

Operating Activities

During the year ended December 31, 2025, net cash provided by operating activities was $1.1 million, primarily due to net income of $5.7 million and non-cash charges of $23.2 million, partially offset by changes in our operating assets and liabilities of $27.8 million. Non-cash charges consisted of stock-based compensation expense of $10.8 million, $8.4 million related to the amortization of right-of-use assets, $4.1 million of depreciation and amortization, partially offset by a $0.2 million gain on sale of property and equipment. Changes in our operating assets and liabilities during the year ended December 31, 2025 consisted of a decrease in accrued liabilities due to SPN of $14.5 million, a decrease in operating lease liabilities of $8.7 million, a decrease in accrued expenses and other liabilities of $6.5 million, a decrease in accounts payable of $2.4 million, and an increase in accounts receivable relating to the CARB-X program of $0.1 million, partially offset by a decrease in prepaid expenses and other current and other non-current assets of $2.7 million and a decrease in accounts receivable due from SPN - related party of $1.7 million.

During the year ended December 31, 2024, net cash used in operating activities was $148.6 million, primarily due to non-cash charges of $83.2 million and changes in our operating assets and liabilities of $65.5 million. Non-cash charges consisted of the $146.7 million gain on sale of VOWST Business and $0.5 million decrease in the fair value of warrants, partially offset by stock-based compensation expense of $21.0 million, $9.2 million related to the amortization of right-of-use assets, $5.5 million of depreciation and amortization, $1.4 million of amortization of debt issuance costs, $23.4 million of loss associated with the extinguishment of the prior credit facility with Oaktree, $0.3 million loss on disposal of fixed assets, and $3.3 million of impairment charges related to our long-lived assets. Changes in our operating assets and liabilities during the year ended December 31, 2024 consisted of a $1.0 million decrease in prepaid expenses and other current and non-current assets, a decrease in inventories of $33.8 million in connection with the sale of VOWST Business to SPN, a $2.9 million decrease in accounts payable, a decrease in deferred income - related party of $4.1 million, a decrease in collaboration receivable - related party of $8.7 million, a decrease in operating lease liabilities of $6.3 million, and a $10.2 million decrease in accrued expenses and other liabilities, partially offset by an increase in accrued liabilities due to SPN - related party of $15.7 million and an increase in accounts receivable due from SPN - related party of $2.1 million. The decrease in inventories, increase in accrued liabilities due to SPN - related party, increase in receivables due from SPN - related party, decrease in deferred income – related party and decrease in collaboration receivable – related party were all related to the sale of the VOWST Business. The decrease in operating lease liabilities was due to the cash payment of lease obligations and the decrease in accounts payable and accrued expenses were the results of payments to vendors and changes in the business following the sale of the VOWST Business.

Investing Activities

During the year ended December 31, 2025, net cash used in investing activities was $0.1 million, consisting of $0.3 million of purchases of property and equipment, partially offset by $0.2 million proceeds from the sale of property and equipment.

During the year ended December 31, 2024, net cash provided by investing activities was $142.3 million, primarily due to $141.3 million of proceeds from the sale of the VOWST Business and $1.4 million sale of a restricted investment relating to a security deposit on one of our leases that was reclassified as restricted cash, partially offset by $0.4 million of purchases of property and equipment.

Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was $13.9 million, consisting of $13.2 million from the issuance of common stock under our at the market equity program, net of issuance costs, $0.5 million from the exercise of stock options, and $0.2 million from the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

During the year ended December 31, 2024, net cash used in financing activities was $90.4 million, consisting of $127.9 million repayment of the prior credit facility with Oaktree, partially offset by $23.5 million from the issuance of common stock under our at the market equity program, net of issuance costs, $13.5 million from the issuance of common stock in connection with the sale of the VOWST Business to SPN, and $0.5 million from the issuance of common stock under our 2015 ESPP.

Funding Requirements

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

- invest in our early-stage pipeline product candidates, including SER-603 in IBD and SER-155 in irEC;
- conduct clinical trials for SER-155 in allo-HSCT and other medically vulnerable populations;
- make strategic investments in manufacturing capabilities;
- maintain and augment our extensive proprietary live biotherapeutic drug development know-how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire;
- establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any other products for which we may obtain regulatory approval;
- perform our obligations under any agreements with collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Because of the numerous risks and uncertainties associated with the development of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the cost of conducting clinical trials for our lead candidate, SER-155 in allo-HSCT and other targeted indications, and other product candidates in our pipeline;
- the total amount of the Milestone Payments we may receive from the Transaction,
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; 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 for our current or future product candidates and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Additionally, part of our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. Additionally, market volatility resulting from macroeconomic conditions, 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 stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. Any 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 stockholders' 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, debt financings, or collaborations when needed, we may be required to delay, limit, reduce or terminate our product development programs or any potential future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As discussed in Note 1 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the consolidated financial statements are issued. The ability to obtain sufficient proceeds from additional equity offerings, collaborations or other financing with terms favorable or acceptable to us cannot be considered probable, as these events are outside of our control. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern. Based on our currently available cash resources, and considering our future operating plans, we anticipate that we will require additional funding following the third quarter of 2026.

Contractual Obligations and Commitments

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

Lease Commitments

Our lease commitments reflect payments due under our operating lease agreements for our corporate headquarters, office and laboratory space, that expire between November 2028 and April 2033. As of December 31, 2025, our contractual commitments for our leases were $118.4 million, of which $20.0 million is expected to be paid within one year, and $98.4 million will be paid over the remaining term of such leases. We do not have any commitment for leases that had not yet commenced as of December 31, 2025. For additional information on our leases and timing of future payments, please read Note 6, *Leases*, to the consolidated financial statements included in this Form 10-K.

Profit Sharing Payments

We and SPN shared 50/50 in the net profit or net loss achieved during the period from the Closing Date until December 31, 2025, or the Profit Sharing Period. During the Profit Sharing Period, we reimbursed SPN for (i) certain payments under the exclusive license agreement between us and Memorial Sloan Kettering Cancer Center, (ii) certain costs incurred in connection with an ongoing post-marketing safety study of VOWST and (iii) 80.1% of all rent and other costs due to the landlord under the lease for our Waltham facility. As of December 31, 2025, the remaining liability associated with all of these obligations was $3.3 million, all of which is expected to be paid within one year.

Other Obligations

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

Recently Issued and Adopted Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Fluctuation Risk

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

As of December 31, 2025, our cash and cash equivalents consisted of cash in operating bank 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 our financial position or results of operations.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

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

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

Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

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

Item 9B. Other Information

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

None.

b) Insider Trading Arrangements and Policies.

On November 25, 2025, Teresa L. Young, Ph.D., our Chief Commercial and Strategy Officer, adopted a Rule 10b5-1 plan (the "Young 10b5-1 Plan") intended to satisfy the affirmative defense of Rule 10b5-1(c) of the Exchange Act. The plan provides for the periodic sale of (1) up to 31,680 shares of common stock and (2) the net number of shares of common stock underlying 1,152

unvested restricted stock units after giving effect to the number of shares to be sold outside of the Young 10b5-1 Plan to satisfy tax withholding obligations (which net amount is not currently determinable) between March 17, 2026 and March 12, 2027, unless otherwise terminated according to its terms.

On November 26, 2025, Kelly Brady, M.S., our Executive Vice President, Chief Operating Officer, adopted a Rule 10b5-1 plan (the "Brady 10b5-1 Plan") intended to satisfy the affirmative defense of Rule 10b5-1(c) of the Exchange Act. The plan provides for the periodic sale of (1) up to 7,611 shares of common stock and (2) the net number of shares of common stock underlying 797 unvested restricted stock units after giving effect to the number of shares to be sold outside of the Brady 10b5-1 Plan to satisfy tax withholding obligations (which net amount is not currently determinable) between March 17, 2026 and November 17, 2026, unless otherwise terminated according to its terms.

Other than the foregoing, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Director Biographical Information

Name	Age	Position
Dennis A. Ausiello, M.D. (3)(4)	80	Director
Stephen Berenson (1)(3)	65	Director
Willard H. Dere, M.D. (1)(4)	72	Director
Claire M. Fraser, Ph.D. (1)(4)	70	Director
Kurt C. Graves (2)	58	Director
Richard N. Kender	70	Executive Chair and Interim Chief Executive Officer
Robert Rosiello (2)	68	Director
Eric D. Shaff	50	Director
Hans-Juergen Woerle, M.D., Ph.D. (4)	60	Director

(1) Member of the audit committee.

(2) Member of the compensation and talent committee.

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

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

Dennis A. Ausiello, M.D., has served as a member of our board of directors since April 2015. Dr. Ausiello has served as the Jackson Distinguished Professor of Clinical Medicine at Harvard Medical School and Director, Emeritus of Harvard Medical School's M.D./Ph.D. Program since 1996, Chair of Medicine, Emeritus, and Director of the Center for Assessment Technology and Continuous Health (CATCH) at Massachusetts General Hospital, which he co-founded, since 2012, and Physician-in-Chief Emeritus at Massachusetts General Hospital since 2013. From 1996 to April 2013, Dr. Ausiello served as the Chief of Medicine at Massachusetts General Hospital. Dr. Ausiello is a member of the Institute of Medicine of the National Academy of Sciences and a fellow of the American Academy of Arts and Sciences. Dr. Ausiello has served on the board of directors of Alnylam Pharmaceuticals since April 2012, and previously served as Vice Chairman of the board of directors of Spexis AG, a clinical-stage biopharmaceutical company, from December 2021 to December 2025 and on the board of directors of Pfizer Inc. from 2006 to 2020, where he currently serves on the advisory board since 2019. Dr. Ausiello also serves on the boards of directors of numerous privately held companies. Dr. Ausiello received a B.A. in Biochemistry from Harvard College and an M.D. from the University of Pennsylvania. We believe that Dr. Ausiello is qualified to serve on our board of directors because of his extensive experience as a physician and as a director of pharmaceutical companies.

Stephen A. Berenson has served as a member of our board of directors since August 2019 and served as our Chairman between December 2019 and March 2026. Mr. Berenson is an Advisor Partner at Flagship Pioneering, a life sciences innovation firm which conceives, creates, resources and develops first-in-category bioplatform companies, after serving as Managing Partner since June 2017. Prior to Flagship, Mr. Berenson spent 33 years in various roles as an investment banker at J.P. Morgan, most recently serving in the role of Vice Chairman of Investment Banking from 2005 to April 2017, where he focused on providing high-touch strategic advice and complex transaction execution to leading companies across all industries globally. He was co-founder of J.P. Morgan's Global Strategic Advisory Council and co-founder of the firm's Board Initiative. Mr. Berenson has served on the board of directors of Inari, a privately held agricultural company, since January 2024. He previously served as chairman of the board of directors of Cellarity, a privately held pharmaceutical company between July 2021and December 2025, as chairman of SAIL Biomedicines, a privately held pharmaceutical company, between August 2024 and December 2025, and on the board of directors of Moderna, Inc., a pharmaceutical and biotechnology company, between October 2017 and August 2024. 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.

Willard H. Dere, M.D., has served as a member of our board of directors since July 2017. Dr. Dere has served as Chief Advisor to the Chief Executive Officer and Chief Medical Officer of Angita Bio, a biotechnology company, since July 2022. Dr. Dere has also been Professor Emeritus, Department of Internal Medicine, at the University of Utah School of Medicine since July 2022. From November 2014 until June 2022, Dr. Dere held multiple roles at the University of Utah Health Sciences Center, including Associate Vice President for Research, Co-Director of the Utah Clinical and Translational Science Institute, and Co-Director of the Center for Genomic Medicine. Prior to his professorship, from 2003 until 2014, Dr. Dere worked at Amgen, where he was Senior Vice President and head of Global Development, and led development programs in multiple therapeutic areas. From 1989 to 2014, he worked at Eli Lilly and led multiple development programs, and also worked in clinical pharmacology, regulatory affairs and safety. Dr. Dere has served on the boards of directors of BioMarin Pharmaceutical, Inc. since 2016 and Metagenomi, Inc. since August 2021, and

previously served on the boards of directors of Mersana Therapeutics, Ocera Therapeutics and Radius Health. Dr. Dere received his B.A. in History and Zoology and M.D. from the University of California, Davis, completed his internal medicine residency training at the University of Utah, and his postdoctoral training in endocrinology and metabolism at the University of California, San Francisco. We believe Dr. Dere is qualified to serve on our board of directors due to his extensive academic experience and his knowledge of the biotechnology industry.

Claire M. Fraser, Ph.D., has served as a member of our board of directors since January 2023. Dr. Fraser has been a faculty member at the University of Maryland School of Medicine in Baltimore, Maryland for the past 19 years and is the Founding Director of the Institute for Genome Sciences and Professor Emerita of Medicine and Microbiology and Immunology. From 1998 to 2007, she served as President and Director of The Institute for Genomic Research, a not-for-profit research organization engaged in human and microbial genomics studies. Dr. Fraser has served on the Board of Directors of Becton, Dickinson, and Company, a medical technology company, since 2006, and previously served as the Chair of the Board and a director of the American Association for the Advancement of Science. Dr. Fraser received her bachelor's degree in Biology from Rensselaer Polytechnic Institute, her Ph.D. in Pharmacology from State University of New York-Buffalo and is an elected member of both the National Academy of Sciences and the National Academy of Medicine. We believe Dr. Fraser is qualified to serve on our board of directors due to her extensive academic experience and her knowledge of the microbiome industry.

Kurt C. Graves has served as a member of our board of directors since November 2015. Mr. Graves has served as the Chairman, President and Chief Executive Officer of i20 Therapeutics, Inc., a biotechnology company, since August 2023, and as a director since August 2021. He previously served as the Executive Chairman of i20 Therapeutics' board of directors from August 2021 to August 2023. Mr. Graves was previously the Chairman, President and Chief Executive Officer of Intarcia Therapeutics, Inc., a biotechnology company, from September 2010 to December 2020, and on its board of directors from August 2010 to December 2020. Previously, he served as Executive Vice President, Chief Commercial Officer and Head of Strategic Development at Vertex Pharmaceuticals Inc., or Vertex, from July 2007 to October 2009. Prior to joining Vertex, Mr. Graves held various senior leadership positions at Novartis Pharmaceuticals Corporation, or Novartis Corp., from 1999 to June 2007, including the Global General Medicines Business Unit Head and Global Chief Marketing Officer for the pharmaceuticals division of Novartis Corp. from September 2003 to June 2007. Prior to Novartis Corp., Mr. Graves held senior leadership positions at Merck and Astra-Merck where he led the U.S. Business Unit responsible for Prilosec, Nexium and Prilosec OTC over a 10-year period. He served as Chairman on the board of directors of Radius Health, Inc. from May 2011 to March 2020, and as a director on Achillion Pharmaceuticals, Inc., or Achillion, from June 2012 to January 2020, when Achillion was acquired. Mr. Graves received a B.S. in Biology from Hillsdale College. We believe Mr. Graves is qualified to serve as a member of our board of directors because of his extensive experience in the life sciences industry, membership on various boards of directors and his leadership and management experience.

Richard N. Kender has served as our Executive Chair and Interim Chief Executive Officer since March 2026 and has been 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 board of directors of Longeveron Inc. since May 2024. He previously served on the boards of directors of Poxel S.A. between March 2015 and July 2025, Bicycle Therapeutics PLC between July 2019 and June 2025, INC Research Holdings, Inc. (now known as Syneos Health) between December 2014 and August 2017, Abide Therapeutics, Inc., a privately held company, between December 2015 and May 2019, Omega Therapeutics between June 2024 and April 2025, and ReViral Ltd., a privately held company, from November 2019 to June 2022. Mr. Kender received a B.S. in Accounting from Villanova University and an M.B.A. from Fairleigh Dickinson University. We believe Mr. Kender is qualified to serve on our board of directors because of his finance experience and knowledge of the biotechnology industry.

Robert Rosiello has served as a member of our board of directors since August 2025. Mr. Rosiello is an Executive Partner at Flagship Pioneering, which he joined in 2018 and where he focuses on building capability to help originate, manage, and grow new Flagship companies. From September 1984 to June 2015, Mr. Rosiello worked at McKinsey & Company advising CEOs and boards of leading health care, technology, and consumer companies. He served as a senior partner for 18 years and was a member of McKinsey's Senior Partner Review and Compensation Committees. Mr. Rosiello led the work that shifted McKinsey's recruiting toward non-MBAs and developed innovative leadership training for McKinsey's senior partners. He also led significant pro bono work for Save the Children, Americares, Carnegie Corporation, and Fairfield University. From July 2015 to August 2016, Mr. Rosiello was both Executive Vice President and Chief Financial Officer at Valeant Pharmaceuticals, where he led the finance, human resources, and IT functions. He led Valeant's financial restatement and regained timely reporting status with the SEC. Mr. Rosiello has served on the Board of the Marine Biological Laboratory, a privately held company, since July 2024, New England Conservatory of Music, a privately held company, since July 2024 and SANA Biotechnology since June 2025. Mr. Rosiello previously served on the boards of Axcella Health, Inc. between October 2022 and November 2023, Evelo Biosciences between April 2023 and November 2023, Inari Agriculture, a privately held company between September 2015 and December 2021 and Omega Therapeutics, Inc between October 2024 and January 2025. Mr. Rosiello also previously served on the Board and Executive Committee of Catholic Charities of New York, between March 2012 and December 2025. Mr. Rosiello received his B.A. in economics from the University of North Carolina, where he was a Morehead Scholar and graduated Phi Beta Kappa, an M.Sc. in economics from the London School of Economics, and an M.B.A. from Harvard

Business School. We believe that Mr. Rosiello's extensive business and financial experience qualifies him to serve on our board of directors.

Eric D. Shaff has served as a member of our board of directors since January 2019. Mr. Shaff has been the President and Chief Executive Officer of PsiThera, Inc. since September 2025. Previously, he served as our President and Chief Executive Officer between January 2019 and July 2025 and as our Chief Operating and Financial Officer and Executive Vice President between January 2018 and January 2019 and as our Chief Financial Officer between November 2014 and January 2019. From January 2012 to November 2014, Mr. Shaff was Vice President of Corporate Finance for Momenta Pharmaceuticals, or Momenta, a biotechnology company, where he helped manage Momenta's accounting, finance, planning, and procurement functions, as well as contributing to Momenta's investor relations efforts. Prior to Momenta, Mr. Shaff held a number of corporate development and finance positions with Genzyme Corporation, a biotechnology company, most recently as Vice President of Finance/Controller for the Personalized Genetic Health division. Mr. Shaff previously served on the board of directors of Sigilon Therapeutics, Inc. from 2017 to August 2023. Mr. Shaff received his B.A. from the University of Pennsylvania and his M.B.A. from Cornell University. We believe Mr. Shaff is qualified to serve on our board of directors because of his extensive business and finance experience and his knowledge of the biotechnology industry.

Hans-Juergen Woerle, M.D., Ph.D., has served as a member of our board of directors since February 2025. Dr. Woerle has served as Chief Medical Officer and Chief Scientific Officer at Nestlé Health Science S.A. since November 2018, where he is responsible for global research and development strategy. Dr. Woerle served on the boards of directors of Cerecin Inc., a clinical-stage biotechnology company, from June 2020 to September 2024 and Enterome, SA, a clinical-stage biopharmaceutical company from June 2020 to March 2025. Dr. Woerle is a board-certified physician and a specialist in internal medicine and endocrinology, holding an adjunct professorship at University of Ulm. Dr. Woerle earned his bachelor's degree, master's degree and medical degree from Ludwig Maximilian University. We believe Dr. Woerle is qualified to serve on our board of directors because of his extensive experience as a physician and in clinical research and development.

Information about our Executive Officers

Name	Age	Position
Richard N. Kender	70	Executive Chair and Interim Chief Executive Officer
Matthew Henn, Ph.D.	51	President and Chief Scientific Officer
Kelly Brady, M.S.	42	Executive Vice President, Chief Operating Officer
Thomas J. DesRosier	71	Executive Vice President, Chief Legal Officer
Marella Thorell	58	Executive Vice President, Chief Financial Officer
Teresa L. Young, Ph.D.,	59	Executive Vice President, Chief Commercial and Strategy Officer

Kelly Brady, M.S. has served as our Executive Vice President, Chief Operating Officer since March 2026. She served as our Senior Vice President, Clinical Development from January 2023 to March 2026, and, prior to this, served as our Vice President, Clinical Operations, Executive Director, Clinical Operations, and Senior Director, Clinical Operations between June 2018 and January 2023. Prior to joining the Company in 2018, Ms. Brady was Senior Director and Global Clinical Program Lead at Akebia Therapeutics, Inc., where she oversaw pivotal programs in anemia due to chronic kidney disease. She also held roles of increasing responsibility in operations and program management at Acetylon Pharmaceuticals, Inc., with the company's eventual acquisition by Celgene Corporation. Earlier in her career, she served as the Global Phase 3 Clinical Operations Leader at Millennium Pharmaceuticals, Inc. (later Takeda Oncology), executing pivotal global oncology trials for ADCETRIS®, and as a member of the operations team at Osiris Therapeutics, Inc., managing global graft-versus-host disease studies for the world's first approved stem-cell therapy Prochymal. Ms. Brady holds a B.S. in Neuroscience from Lafayette College and an M.S. in Biotechnology from Johns Hopkins University.

Thomas J. DesRosier has served as our Chief Legal Officer, Executive Vice President, and Secretary since May 2016. He has also served as our Co-President/Chief Executive Officer from July 2025 to March 2026. From 2015 to 2016, Mr. DesRosier served as Executive Vice President, Chief Legal and Administrative Officer and Secretary of ARIAD Pharmaceuticals, Inc., a biopharmaceutical company, from 2014 to 2015 as Executive Vice President, Chief Legal and Administrative Officer and Secretary of Cubist Pharmaceuticals, Inc., or Cubist, a biopharmaceutical company, and from 2013 to 2014 as Senior Vice President, Chief Legal Officer and Secretary of Cubist. Before that, Mr. DesRosier served as Senior Vice President, General Counsel North America of Sanofi from 2011 to 2013. From 1999 to 2011, Mr. DesRosier held leadership roles of increasing seniority within the legal group of Genzyme Corporation, a biotechnology company, culminating in his role as Senior Vice President, Chief Legal Officer. Mr. DesRosier has served as a member of the board of directors of Avanir Pharmaceuticals, a privately held company and wholly-owned subsidiary of Otsuka Pharmaceutical Company, Ltd., since June 2017. Mr. DesRosier earned a B.A. in Chemistry from the University of Vermont and a J.D. from Wake Forest University School of Law.

Matthew Henn, Ph.D., has served as our President and Chief Scientific Officer since March 2026. He has also served as our Executive Vice President and Chief Scientific Officer from February 2019 to March 2026. Dr. Henn has been involved in the discovery and development of multiple live biotherapeutics, including two breakthrough therapy designated biologics, across infectious, inflammatory, and oncology indications, and has authored over 75 peer-reviewed publications. He has extensive research experience in microbiology, genomics, and computational biology, as well as in drug pharmacology and clinical translation. His research has focused on microbial populations and the functional role of microbes in both environmental and human disease applications, and the development of genomic and functional screening technologies to study these populations. Prior to joining Seres in 2012, he was the Director of Viral Genomics and Assistant Director of the Genome Sequencing Center for Infectious Diseases at the Broad Institute of Massachusetts Institute of Technology and Harvard. He has served on various National Institutes of Health, or NIH, working groups on antimicrobial resistance and microbiome research, as a scientific advisor for NIH's Viral Pathogen Bioinformatics Resource Center, as an ad-hoc reviewer and editor of various peer-reviewed journals, and as a scientific advisor to non-profit and for-profit organizations. He currently serves on the Microbiome Therapeutics Innovation Group board of directors, the World Microbiome Partnership steering committee, and Life Sciences Cares board of advisors. Dr. Henn is formally trained in ecology and evolutionary biology and earned his Ph.D. in ecosystem sciences from the University of California at Berkeley, where he was a NASA Earth Systems Sciences Fellow, and trained as a National Science Foundation Postdoctoral Fellow in Microbiology at Duke University.

Marella Thorell has served as our Executive Vice President and Chief Financial Officer since March 2024. She has also served as our Co-President/Chief Executive Officer from August 2025 to March 2026. From September 2022 to December 2023, Ms. Thorell served as the Chief Financial Officer and Treasurer of Evelo Biosciences, Inc., a biotechnology company. From January 2021 to July 2022, she served as Chief Accounting Officer and previously as Head of Finance at Centessa Pharmaceuticals PLC, or Centessa, a pharmaceutical company. In that role, she led the establishment of Centessa's finance operations, led its public company readiness activities in connection with its initial public offering, and oversaw accounting operations. Previously, from October 2019 to December 2020, Ms. Thorell served as Chief Financial Officer at Palladio Biosciences, a biotechnology company, prior to its acquisition by Centessa. Before that, Ms. Thorell spent over ten years at Realm Therapeutics PLC, a biopharmaceutical company,

serving in various roles of increasing responsibility, including Chief Financial Officer and Chief Operating Officer. Ms. Thorell served on the board of directors and as the Audit Committee Chair of Carisma Therapeutics, a biopharmaceutical company, from June 2024 through December 2025 and previously served on the boards of directors of ESSA Pharma Inc., a pharmaceutical company from July 2019 to October 2025, and Vallon Pharmaceuticals, Inc., a pharmaceutical company, from February 2021 until its reverse-merger with GRI Bio in April 2023. Ms. Thorell holds a B.S. in Business from Lehigh University.

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

Code of Ethics

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

Other

The remainder of the information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2026 and is incorporated herein by reference.

Item 11. Executive Compensation

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2026 and is incorporated herein by reference.

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

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2026 and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2026 and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required to be disclosed by this item will be contained in the Proxy Statement for our Annual Meeting of Stockholders to be held in 2026 and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statements Schedules

(a)(1) Financial Statements.

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

(a)(2) Financial Statement Schedules.

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

(a)(3) Exhibits.

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

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
2.1^	Asset Purchase Agreement, dated August 5, 2024, by and between the Registrant and Société des Produits Nestlé S.A.	8-K	001-37465	2.1	8/6/24	
3.1	Restated Certificate of Incorporation	8-K	001-37465	3.1	7/1/15	
3.2	Certificate of Amendment to Restated Certificate of Incorporation of Registrant, dated June 27, 2023	8-K	001-37465	3.1	6/28/23	
3.3	Certificate of Amendment to Restated Certificate of Incorporation of Registrant, dated April 5, 2024	8-K	001-37465	3.1	4/8/24	
3.4	Certificate of Amendment to Restated Certificate of Incorporation of Registrant, dated April 21, 2025	8-K	001-37465	3.1	4/22/25	
3.5	Amended and Restated Bylaws	8-K	001-37465	3.1	1/2/24	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-204484	4.2	6/16/15	
4.2	Description of Capital Stock					*
4.3	Form of Warrant, dated April 27, 2023, issued by the Registrant to the Lenders, together with a schedule of warrant holders	8-K	001-37465	4.1	4/27/23	
10.1#	2025 Incentive Award Plan, as amended and forms of award agreements thereunder	8-K	001-37465	10.1	4/14/25	
10.2#	2015 Incentive Award Plan, as amended and forms of award agreements thereunder	10-K	001-37465	10.1	3/7/23	
10.3#	2015 Employee Stock Purchase Plan	S-1/A	333-204484	10.3	6/16/15	
10.4#	2012 Stock Incentive Plan, as amended and form of option agreement thereunder	S-1	333-204484	10.1	5/27/15	
10.5#	2022 Employment Inducement Award Plan and forms of award agreements thereunder	10-K	001-37465	10.4	3/7/23	
10.6#	Non-Employee Director Compensation Program	10-Q	001-37465	10.2	5/7/25	
10.7	Lease, dated September 22, 2021, by and between the Registrant and HCP/KING 101 CPD LLC	10-K	001-37465	10.6	3/5/24	
10.8#	Second Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Eric D. Shaff	8-K	001-37465	10.1	2/1/21	
10.9#	Letter Agreement, dated July 21, 2025, by and between the Company and Eric D. Shaff	10-Q	001-37465	10.1	8/6/25	

10.10#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Thomas J. DesRosier	8-K	001-37465	10.2	2/1/21	
10.11#	Letter Agreement, dated July 21, 2025, by and between the Company and Thomas J. DesRosier	10-Q	001-37465	10.3	8/6/25	
10.12#	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	
10.13#	Retention Agreement, dated October 5, 2025, by and between the Company and Matthew R. Henn, Ph.D.	10-Q	001-37465	10.1	11/5/25	
10.14#	Letter Agreement dated March 2, 2026, by and between the Company and Matthew Henn, Ph.D.	8-K	001-37465	10.2	3/2/26	
10.15#	Amended and Restated Employment Agreement, dated January 29, 2021, by and between the Registrant and Teresa L. Young	10-K	001-37465	10.13	3/2/21	
10.16#	Retention Agreement, dated October 2, 2025, by and between the Company and Teresa L. Young	10-Q	001-37465	10.2	11/5/25	
10.17#	Employment Agreement, dated February 24, 2024, by and between the Registrant and Marella Thorell	10-Q	001-37465	10.1	5/8/24	
10.18#	Letter Agreement, dated July 21, 2025, by and between the Company and Marella Thorell	10-Q	001-37465	10.2	8/6/25	
10.19#	Amended and Restated Employment Agreement, dated March 18, 2025, by and between the Company and Kelly M. Brady					*
10.20#	Letter Agreement dated March 2, 2026, by and between the Company and Kelly M. Brady	8-K	001-37465	10.1	3/2/26	
10.21#	Employment Letter Agreement dated March 2, 2026, by and between the Company and Richard N. Kender	8-K	001-37465	10.3	3/2/26	
10.22	Securities Purchase Agreement, dated September 30, 2024, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.1	10/1/24	
10.23†	Transition Services Agreement, dated September 30, 2024, by and between Seres Therapeutics, Inc. and Nestlé Enterprises S.A.	8-K	001-37465	10.2	10/1/24	
10.24	Cross-License Agreement, dated September 30, 2024, by and between Seres Therapeutics, Inc. and Société des Produits Nestlé S.A.	8-K	001-37465	10.3	10/1/24	
10.25	Securities Purchase Agreement, dated August 12, 2020 by and between the Company and Société des Produits Nestlé S.A.	8-K	001-37465	10.1	8/14/20	
10.26#	Form of Performance Option Agreement under the 2015 Incentive Award Plan	10-Q	001-37465	10.6	5/8/24	
19.1	Seres Therapeutics, Inc. Insider Trading Compliance Policy	10-K	001-37465	19.1	3/13/25	
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 Interim Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*

32.1	Section 1350 Certification of Interim Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
97.1#	Policy for Recovery of Erroneously Awarded Compensation	10-K	001-37465	97.1	3/5/24	
101.INS	Inline XBRL Instance Document- the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.
Indicates management contract or compensatory plan.
^ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv). Such omitted information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

SERES THERAPEUTICS, INC.

Date: March 12, 2026

By: /s/ Richard N. Kender
Richard N. Kender
Executive Chair and Interim Chief Executive Officer

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

Signature	Title	Date
/s/ Richard N. Kender Richard N. Kender	Executive Chair and Interim Chief Executive Officer (Principal Executive Officer)	March 12, 2026
/s/ Marella Thorell Marella Thorell	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 12, 2026
/s/ Stephen Berenson Stephen Berenson	Director	March 12, 2026
/s/ Dennis A. Ausiello Dennis A. Ausiello, M.D.	Director	March 12, 2026
/s/ Rob Rosiello Rob Rosiello	Director	March 12, 2026
/s/ Willard H. Dere Willard H. Dere, M.D.	Director	March 12, 2026
/s/ Claire M. Fraser Claire M. Fraser, Ph.D.	Director	March 12, 2026
/s/ Kurt C. Graves Kurt C. Graves	Director	March 12, 2026
/s/ Hans-Juergen Woerle, M.D., Ph.D. Hans-Juergen Woerle, M.D., Ph.D.	Director	March 12, 2026
/s/ Eric D. Shaff Eric D. Shaff	Director	March 12, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements

We have audited the accompanying consolidated balance sheets of Seres Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive income (loss), of stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2025, 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, 2025 and 2024**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America.

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

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company incurred recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

Research and Development Expenses Associated with Other Operational Costs

As described in Note 2 to the consolidated financial statements, research and development costs are expensed as incurred. Research and development expenses include 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, and certain costs of fulfilling the Company's obligations under the Transition Services Agreement (TSA). The Company's research and development expense for the year ended December 31, 2025 was $49.1 million, a significant portion of which is associated with other operational costs.

The principal consideration for our determination that performing procedures relating to research and development expenses associated with other operational costs is a critical audit matter is a high degree of auditor effort in performing procedures related to research and development expenses associated with other operational costs.

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, testing research and development expenses associated with other operational costs on a sample basis by obtaining and inspecting source documents, such as underlying agreements with outside vendors, purchase orders and invoices received, where applicable.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 12, 2026

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,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 45,766	$ 30,793
Accounts receivable due from SPN - related party	360	2,068
Accounts receivable	157	—
Prepaid expenses and other current assets (1)	3,093	5,813
Total current assets	49,376	38,674
Property and equipment, net	7,635	11,534
Operating lease assets	72,483	80,903
Restricted cash	8,668	8,668
Other non-current assets	31	31
Total assets	$ 138,193	$ 139,810
Liabilities and Stockholder's Equity		
Current liabilities:		
Accounts payable	$ 1,682	$ 4,079
Accrued expenses and other current liabilities	3,972	10,719
Accrued liabilities due to SPN - related party	3,278	17,750
Operating lease liabilities	10,390	8,674
Total current liabilities	19,322	41,222
Operating lease liabilities, net of current portion	72,576	82,966
Other long-term liabilities	2,077	1,838
Total liabilities	93,975	126,026
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2025 and 2024; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.001 par value; 360,000,000 shares authorized at December 31, 2025 and 2024, respectively; 9,556,446 and 8,650,227 shares issued and outstanding at December 31, 2025 and 2024, respectively	10	9
Additional paid-in capital	1,016,611	991,874
Accumulated deficit	(972,403)	(978,099)
Total stockholders' equity	44,218	13,784
Total liabilities and stockholders' equity	$ 138,193	$ 139,810

[1] Includes $0 as of December 31, 2025 and $2,683 as of December 31, 2024 of unbilled receivable from SPN (related party) related to certain costs of the transition services performed by the Company. See Note 3, *Discontinued Operations and TSA*, for further details.

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

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

	Year Ended December 31,		
	2025	2024	2023
Revenue:			
Grant revenue	789	—	—
Total revenue	789	—	—
Operating expenses:			
Research and development expenses	$ 49,060	$ 64,600	$ 117,597
General and administrative expenses	39,156	53,183	77,500
Manufacturing services	6,544	3,532	—
Total operating expenses	94,760	121,315	195,097
Loss from operations	(93,971)	(121,315)	(195,097)
Other income (expense):			
Gain on sale of VOWST Business	80,685	5,684	—
Interest income	2,227	3,967	7,301
Interest expense	—	—	(2,468)
Other income (expense), net (2)	16,755	(14,107)	134
Total other income (expense), net	99,667	(4,456)	4,967
Net income (loss) from continuing operations	$ 5,696	$ (125,771)	$ (190,130)
Net income from discontinued operations, net of tax	$ —	$ 125,907	$ 76,406
Net income (loss)	$ 5,696	$ 136	$ (113,724)
Net income (loss) from continuing operations per share attributable to common stockholders - basic	$ 0.64	$ (16.20)	$ (29.71)
Net income from discontinued operations per share attributable to common stockholders - basic	$ —	$ 16.20	$ 11.94
Net income (loss) per share attributable to common stockholders - basic	$ 0.64	$ —	$ (17.77)
Net income (loss) from continuing operations per share attributable to common stockholders - diluted	$ 0.64	$ (16.20)	$ (29.71)
Net income from discontinued operations per share attributable to common stockholders - diluted	$ —	$ 16.20	$ 11.94
Net income (loss) per share attributable to common stockholders - diluted	$ 0.64	$ —	$ (17.77)
Weighted average common shares outstanding - basic	8,858,975	7,769,910	6,400,339
Weighted average common shares outstanding - diluted	8,869,742	7,769,910	6,400,339
Other comprehensive income:			
Unrealized gain on investments, net of tax of $0	—	—	10
Currency translation adjustment	—	—	2
Total other comprehensive income	—	—	12
Comprehensive income (loss)	$ 5,696	$ 136	$ (113,712)

[2] Includes $13,311 and $6,292 for the years ended December 31, 2025 and 2024 related to reimbursement received from SPN (related party) for transition services provided by the Company.

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	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Par Value				
Balance at December 31, 2022	6,261,400	$ 6	$ 875,300	$ (12)	$ (864,511)	$ 10,783
Issuance of common stock upon exercise of stock options	13,028	—	877	—	—	877
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	61,958	—	—	—	—	—
Issuance of common stock under ESPP	30,133	—	2,151	—	—	2,151
Issuance of common stock from at the market equity offering, net of issuance costs of $772	385,554	1	18,158	—	—	18,159
Issuance of warrants	—	—	2,785	—	—	2,785
Stock-based compensation expense	—	—	34,101	—	—	34,101
Other comprehensive income	—	—	—	12	—	12
Net loss	—	—	—	—	(113,724)	(113,724)
Balance at December 31, 2023	6,752,073	7	933,372	—	(978,235)	(44,856)
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	123,602	—	—	—	—	—
Issuance of common stock under ESPP	29,421	—	487	—	—	487
Issuance of common stock from at the market equity offering, net of issuance costs of $867	1,030,846	1	23,529	—	—	23,530
Issuance of common stock from Securities Purchase Agreement - related party	714,285	1	13,515	—	—	13,516
Stock-based compensation expense	—	—	20,971	—	—	20,971
Net income	—	—	—	—	136	136
Balance at December 31, 2024	8,650,227	9	991,874	—	(978,099)	13,784
Issuance of common stock upon exercise of stock options	23,900	—	501	—	—	501
Issuance of common stock upon vesting of RSUs and PSUs, net of tax withholdings	124,855	—	—	—	—	—
Issuance of common stock under ESPP	17,839	—	230	—	—	230
Issuance of common stock from at the market equity offering, net of issuance costs of $498	739,545	1	13,166	—	—	13,167
Stock-based compensation expense	—	—	10,840	—	—	10,840
Adjustment for fractional shares due to reverse stock split	100	—	—	—	—	—
Net income	—	—	—	—	5,696	5,696
Balance at December 31, 2025	9,556,466	$ 10	$ 1,016,611	$ 0	$ (972,403)	$ 44,218

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,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net income (loss)	$ 5,696	$ 136	$ (113,724)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	10,840	20,971	34,101
Depreciation and amortization expense	4,133	5,468	6,243
Non-cash operating lease cost	8,420	9,230	8,871
Net (accretion) amortization of (discounts) premiums on investments	—	—	(236)
Gain on sale of VOWST Business, net of transaction costs	—	(146,707)	—
Amortization of debt issuance costs	—	1,413	1,139
Loss associated with extinguishment of debt	—	23,351	1,625
(Gain)/loss on disposal of fixed assets	(192)	317	—
Impairment of long-lived assets	—	3,267	—
Change in fair value of warrant liabilities	—	(546)	(1,554)
Collaboration (profit) loss sharing - related party (1)	—	—	5,158
Changes in operating assets and liabilities:			
Accounts receivable due from SPN - related party	1,708	(2,068)	—
Prepaid expenses and other current and non-current assets	2,720	987	(29,124)
Accounts receivable	(157)	—	—
Collaboration receivable - related party	—	8,674	(8,674)
Inventories	—	(33,795)	(29,647)
Deferred income - related party	—	(4,124)	7,730
Deferred revenue - related party	—	—	(1,325)
Accounts payable	(2,397)	(2,940)	(11,578)
Accrued liabilities due to SPN - related party	(14,472)	(15,708)	—
Operating lease liabilities	(8,674)	(6,339)	(2,197)
Accrued expenses and other current and long-term liabilities	(6,508)	(10,196)	15,838
Net cash provided by (used in) operating activities	1,117	(148,609)	(117,354)
Cash flows from investing activities:			
Purchases of property and equipment	(252)	(380)	(7,975)
Proceeds from sales of property and equipment	210	—	—
Purchases of investments	—	—	(4,426)
Sales and maturities of investments	—	—	22,983
Sales of restricted investments	—	1,401	—
Proceeds from sale of VOWST Business	—	141,272	—
Net cash (used in) provided by investing activities	(42)	142,293	10,582
Cash flows from financing activities:			
Proceeds from at the market equity offering, net of issuance costs	13,167	23,530	18,159
Proceeds from exercise of stock options	501	—	877
Proceeds from Securities Purchase Agreement - related party	—	13,516	—
Issuance of common stock under ESPP	230	487	2,151
Proceeds from issuance of debt, net of issuance costs	—	—	103,378
Repayment of notes payable	—	(127,905)	(52,860)
Net cash provided by (used in) financing activities	13,898	(90,372)	71,705
Net increase (decrease) in cash, cash equivalents and restricted cash	14,973	(96,688)	(35,067)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	(1)	2
Cash, cash equivalents and restricted cash at beginning of year	39,461	136,150	171,215
Cash, cash equivalents and restricted cash at end of year	$ 54,434	$ 39,461	$ 136,150
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ 10,858	$ 12,547
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ —	$ 16
Lease liability arising from obtaining right-of-use assets	$ —	$ —	$ 3,046
Prepaid rent reclassified to right-of-use assets	$ —	$ —	$ 4,634
Recognition of warrant liabilities	$ —	$ —	$ 2,100
Warrants issued related to prior credit facility with Oaktree and recorded as debt discount	$ —	$ —	$ 2,785

[1] Includes non-cash collaboration profits and losses related to pre-launch activities; subsequent to the approval of VOWST in April 2023, collaboration (profit) loss sharing - related party is included within changes in operating assets and liabilities.

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 clinical-stage company focused on improving patient outcomes in medically vulnerable populations through discovery and development of novel live biotherapeutics. The Company led the successful development and approval of VOWST (previously referred to as SER-109), the first FDA-approved orally administered microbiome therapeutic and a Breakthrough Therapy designated drug, which was sold to Nestlé Health Science (as defined below) in September 2024. The Company's live biotherapeutic product ("LBP") candidates, including SER-155, SER-603, SER-147, and other potential candidates in earlier development, are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. The Company is designing LBP candidates to target the prevention and treatment of a broad swath of infections, and to treat inflammatory and immune ("I&I") diseases by modulating host function to increase epithelium integrity and to induce immune homeostasis and tolerance, as well as to prevent the colonization and overgrowth of pathogens in the gastrointestinal ("GI") tract.

SER-155, the Company's most advanced LBP candidate, is an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial bloodstream infections ("BSIs"), including those that can harbor antimicrobial resistance ("AMR"), as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation ("allo-HSCT"). In the Company's placebo-controlled Phase 1b study of SER-155 in allo-HSCT, SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post HSCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HSCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with its CRO, and manufacturing of drug substance, the Company has paused additional investment in that program while continuing to seek funding for the Phase 2 study.

The clinical data from the SER-155 Phase 1b study in allo-HSCT, along with the Company's extensive preclinical and translational clinical data compiled over the past decade support and inform the advancement of the Company's earlier stage programs targeting I&I diseases. The Company is evaluating SER-155 in immune checkpoint-related enterocolitis, or irEC, and the Company is developing SER-603, broadly in inflammatory bowel disease, or IBD, including ulcerative colitis, or UC, and Crohn's disease. The Company is currently exploring potential collaborations related to those I&I disease programs.

The Company has built and deploys a reverse translational platform and knowledge base for the discovery and development of live biotherapeutics, and maintains extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for live biotherapeutics; and a strain library and associated microbiological capabilities that spans broad biological and functional breadth. This platform and knowledge base are integrated through a proprietary knowledge graph and agentic artificial intelligence, enabling rapid identification of specific microbes, microbial genes, and microbial metabolites/peptides associated with disease and the design of therapeutic consortia of bacteria for specific pharmacological properties to restructure the gut microbiome and modulate functional pathways associated with disease. In addition, the Company owns a valuable intellectual property estate related to the development and manufacture of live biotherapeutics.

At a special meeting of stockholders held on September 26, 2024, the Company's stockholders approved, and on September 30, 2024 (the "Closing Date"), the Company completed, the sale (the "Transaction") of its VOWST microbiome therapeutic business (the "VOWST Business"), including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of the microbiome product sold under the brand name VOWST as provided for in accordance with the terms of the Purchase Agreement (the "Product"), to Société des Produits Nestlé S.A. ("SPN"), a wholly-owned subsidiary of Nestlé S.A., and its designated affiliates (collectively, "Nestlé Health Science") pursuant to the Asset Purchase Agreement, dated as of August 5, 2024 (the "Purchase Agreement"), by and among the Company and SPN, and a wholly-owned subsidiary of Nestlé S.A. As consideration for the Transaction, SPN paid or agreed to pay, as applicable, the following Transaction Consideration:

(i) a cash payment, which was paid upon completion of the Transaction ("Closing"), of $100,000, less approximately $17,857 owed by the Company to an affiliate of SPN as of March 31, 2024 under the prior license agreement between the Company and the SPN affiliate, less approximately CHF 2,000 in satisfaction of fees due under the Bacthera Manufacturing Agreement (defined below);

(ii) cash installment payments of $50,000, which was received on January 15, 2025 and $25,000, which was received on July 1, 2025 (offset by $1,421 paid by the Company to Nestlé on July 1, 2025 related to certain employment obligations assumed by SPN, as described below), conditioned on the Company's material compliance with obligations under the Transition

Services Agreement (the "TSA") (as described below) entered into at Closing between the Company and Nestlé Enterprises S.A., an affiliate of SPN, or NESA;

(iii) prepayment of the $60,000 milestone payment tied to the achievement of worldwide annual net sales of the Product of $150,000 (the "First Sales Milestone"), which was paid in cash at Closing (the "Prepaid Milestone"), which Prepaid Milestone will accrue interest at a fixed rate of 10% per annum until the First Sales Milestone is achieved and 5% per annum thereafter until the earlier of (x) the date on which the Prepaid Milestone, plus accrued interest thereon, has been repaid in full by set-off and (y) the last day of the Milestone Period (as defined below); and

(iv) future milestone payments of (x) $125,000 tied to the achievement of worldwide annual net sales of the Product of $400,000 and (y) $150,000 tied to the achievement of worldwide annual net sales of the Product of $750,000, during the period from Closing until December 31 of the calendar year in which the tenth anniversary of Closing occurs (the "Milestone Period") (together, the "Future Milestone Payments" and, together with the Prepaid Milestone, the "Milestone Payments").

As they are earned, the Milestone Payments will be satisfied as follows: (i) first, by set-off against all accrued interest on the Prepaid Milestone until the amount of such accrued interest has been paid in full, (ii) second, by set-off against the outstanding balance of the Prepaid Milestone until the Prepaid Milestone has been repaid in full and (iii) thereafter, in cash. If any amount of the Prepaid Milestone (and any accrued interest thereon) remains outstanding as of following the last day of the Milestone Period (defined below), the balance thereof (together with any interest accrued thereon) will be forgiven and the right of set-off of SPN with respect thereto will be deemed forfeited. The installment payment received on July 1, 2025 was offset by $1,421 paid by the Company to Nestlé on the same date related to certain employment obligations assumed by SPN with respect to the period ended as of the Closing Date.

The Company and SPN shared 50/50 in the net profit or net loss (the "Profit Sharing Payments") achieved during the period from the date of Closing until December 31, 2025 (the "Profit Sharing Period"), with the net profit or net loss calculated as (i) the net sales of VOWST in the United States and Canada, plus (ii) other income received in connection with the grant of a license or sublicense with respect to VOWST in the United States and Canada as described in the Purchase Agreement, minus (iii) allowable expenses directly attributable or reasonably allocable to certain development activities, commercialization activities, medical affairs activities, manufacturing activities or other relevant activities, as described in the Purchase Agreement. During the Profit Sharing Period, the Company reimbursed SPN for (i) certain payments under the exclusive license agreement between the Company and Memorial Sloan Kettering Cancer Center, (ii) certain costs incurred in connection with an ongoing post-marketing safety study of VOWST and (iii) 80.1% of all rent and other costs due to the landlord under the lease for the Company's Waltham facility.

At Closing, in exchange for a payment to be made by SPN to Bacthera AG, the Long Term Manufacturing Agreement, dated November 8, 2021 between the Company and Bacthera AG (the "Bacthera Manufacturing Agreement") was terminated and each of Bacthera and Seres released one another from any and all losses, liabilities or other obligations arising thereunder with respect to the period ending at the Closing Date, including without limitation any milestone payments required to be paid to Bacthera thereunder.

On the Closing Date, the Company and SPN entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which SPN purchased 714,285 shares (the "Shares") of common stock at Closing, at a purchase price per share of $21.00, for an aggregate purchase price of $15,000. Under the terms of the Securities Purchase Agreement, SPN agreed not to sell or transfer the Shares for a period of six months after Closing, subject to certain customary exceptions. The Company agreed to register the resale of the Shares by SPN within 90 days of Closing. On October 1, 2024, the Company filed a registration statement to register the Shares, which became effective on October 11, 2024. In addition, under the terms of the Securities Purchase Agreement, for as long as SPN, together with its affiliates, beneficially owns at least 10% of the Company's outstanding shares of common stock, the Company has agreed to take such action within its control to include one individual designated by SPN in the slate of nominees recommended by the Company's board of directors (or the applicable committee of the board of directors) to the Company's stockholders for election to the board of directors at the applicable stockholder meeting. SPN designated Hans-Juergen Woerle, M.D., Ph.D. and on February 4, 2025, the Company's board of directors appointed Dr. Woerle to the board as a Class III director, with a term expiring at the Company's 2027 annual meeting of stockholders. The Securities Purchase Agreement contains customary representations and warranties and closing conditions.

On the Closing Date, the Company entered into a TSA with NESA, which provides for services to be performed by the Company in order to facilitate a transition of the business associated with the VOWST Business to NESA and its affiliates. The scope of the transition services includes the provision of certain manufacturing services and certain administrative functions related to the VOWST Business and operations, including the maintenance of certain manufacturing services and the related facility in which such services are currently conducted. The Company provided the manufacturing services until December 31, 2025 and other services for the duration specified in the schedule to the TSA for each service. NESA paid the Company for certain fixed costs, including a monthly fixed fee and a variable per batch fee for preserved raw material suspension ("PRMS") manufacturing, and reimbursed the Company for certain costs of the transition services performed by the Company under the TSA, including labor. The know-how and other intellectual property

generated in connection with the performance of the TSA will be owned by NESA with the Company having a non-exclusive license to such know-how and other intellectual property under the Cross-License Agreement. During the term of the TSA, the Company transferred the specifications for materials and documentation necessary to enable PRMS manufacturing services to a third party service provider designated by NESA. In the event of a material failure by the Company to deliver PRMS under the TSA, NESA had step-in rights to negotiate to enter into a direct lease with the landlord of the manufacturing facility with respect to the portion of such facility used in connection with the VOWST Business or to cause such services to be performed, with any reasonable out-of-pocket costs and expenses incurred in connection therewith reimbursed by the Company.

At the Closing Date, the Company entered into a cross-license agreement with SPN under which the Company granted to SPN a perpetual, worldwide, non-exclusive, fully paid-up license under certain Company patents that have been issued or will issue in the future and current know-how controlled by the Company that is not transferred to SPN pursuant to the Purchase Agreement. In the field of the treatment of *Clostridioides difficile* infections ("CDI") and recurrent CDI and associated complications (collectively, the "CDI Field") the license to SPN under such Company patents and know-how will be exclusive to SPN for five years after Closing and co-exclusive between SPN and the Company following that five year period. The license from the Company to SPN is to issued Company patents that currently or in the future cover the Product or improvements thereof, and know-how that is used or reasonably useful in connection with the exploitation of the VOWST Business. The Company also granted SPN an exclusive, perpetual, worldwide, fully paid-up license under issued Company patents that currently or in the future cover the Product and improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the Product to exploit SER-262 in the CDI Field. SPN granted to the Company a perpetual, worldwide, non-exclusive license under the patents and know-how that are transferred to SPN pursuant to the Purchase Agreement or developed under the TSA, for the Company's products for use outside of the CDI Field, and after five years from Closing for Company products containing designed, cultivated, bacterial consortia not manufactured using human stool (excluding SER-262) in the CDI Field. From and after Closing, certain license agreements between the Company, SPN, and/or their respective affiliates terminated and are of no further force or effect, except as contemplated by the Purchase Agreement. For example, on September 30, 2024, in connection with the Transaction, the 2016 License Agreement (the "2016 License Agreement") with Nestec, Ltd., as succeeded by SPN (together with NHSc Rx License GmbH, their affiliates, and their subsidiaries "Nestlé"), and the 2021 License Agreement (the "2021 License Agreement") with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with Société des Produits Nestlé S.A, their affiliates, and their subsidiaries "Nestlé") were terminated upon mutual agreement of the parties, with provisions related to record retention, confidentiality obligations, indemnification obligations, intellectual property ownership, and any outstanding payment obligations surviving the termination of each of the 2016 License Agreement and 2021 License Agreement, respectively.

On the Closing Date, the parties entered into assignment and assumption of lease agreements (the "Assignment and Assumption Agreements"). Under the Assignment and Assumption Agreements, the Company assigned to SPN the Company's rights in, to and under certain real property leases, and SPN assumed the liabilities related thereto.

On the Closing Date, the parties entered into an employee support agreement (the "Employee Support Agreement"). Under the Employee Support Agreement, among other things and subject to the terms and conditions therein, certain employees of the Company related to the VOWST Business who accepted employment with SPN or one of its designated affiliates provided the services they provided to the Company prior to the Transaction to SPN, as well as other services as SPN may reasonably request, from Closing until the day prior to the beginning of SPN's or its designated affiliate's next pay period following the Closing. SPN reimbursed the Company's out of pocket costs in connection with such employees' services, including certain compensation and benefits paid or provided to such employees pursuant to the terms of the Employee Support Agreement. All such employees were transferred to SPN as of December 31, 2024.

In connection with the Transaction, the Company fully retired its senior secured debt facility with Oaktree Capital Management. The Company intends to use the remaining proceeds to support the further advancement of SER-155 and the Company's other wholly-owned cultivated live biotherapeutic candidates for medically vulnerable patient populations with potential to address large commercial opportunities.

The Company incurred certain significant costs relating to the Transaction, such as legal, accounting, financial advisory, printing and other professional services fees, as well as other customary payments. For the year ended December 31, 2024, these costs amounted to approximately $9,016, which is included within the net income (loss) from discontinued operations, net of tax line item on the Company's consolidated statements of operations.

Going Concern

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. The Company operates in an environment of rapid change in technology and substantial

competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The accompanying consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of December 31, 2025, the Company had an accumulated deficit of $972,403 and cash and cash equivalents of $45,766.

The Company's product candidates are in development, and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to potential commercialization. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, or maintained, that any product candidate developed will obtain necessary government regulatory approval, or that any approved product will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

Primarily as a result of the costs associated with continuing the research and development efforts for SER-155 and the Company's live biotherapeutics platform, the Company incurred a loss from operations of $93,971 and had operating cash outflows of $73,883, excluding the $75,000 installment payments received from Nestlé, for the year ended December 31, 2025. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. Based on the Company's currently available cash resources, current and forecasted level of operations, and forecasted cash flows for the 12-month period subsequent to the date of issuance of these consolidated financial statements, the Company will require additional funding to support its ongoing operations and meet its obligations as they come due. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due, and to generate profitable operations in the future. Management plans to provide for the Company's capital requirements through financing or other strategic transactions, including potential business development transactions, and selling shares under the Company's at the market equity offering. There can be no assurance that the Company will be able to raise additional capital to fund operations with terms acceptable to the Company, or at all. Because certain elements of management's plans to mitigate the conditions that raised substantial doubt about the Company's ability to continue as a going concern are outside of the Company's control, including the ability to raise capital through an equity or other financing, those elements cannot be considered probable according to Accounting Standards Codification ("ASC") 205-40, *Going Concern* ("ASC 205-40"), and therefore cannot be considered in the evaluation of mitigating factors. As a result, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for 12 months from the date these consolidated financial statements are issued. The accompanying consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Reclassifications

Certain amounts in prior periods have been reclassified to reflect the impact of the discontinued operations treatment of the VOWST Business.

On April 21, 2025, the Company effected a 1-for-20 reverse stock split of the Company's common stock. All share and per share amounts in the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. Therefore, the Company reclassified an amount equal to the reduction in the number of shares of common stock at par value to additional paid-in capital. No fractional shares were issued in connection with the reverse split, and stockholders who would otherwise be entitled to receive a fractional share instead received a cash payment equal to the fraction of a share of common stock in lieu of such fractional share. Proportionate adjustments were made to the number of shares authorized under the Company's equity incentive plans, the number of shares subject to any award or purchase right under the Company's equity incentive plans, and the exercise price or purchase price with respect to any stock option award or purchase right under the Company's equity incentive plans. See Note 7, *Stock and Stock-Based Awards*, for further information.

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

Discontinued Operations

The Company accounted for the sale of its VOWST Business in accordance with ASC 205 *Discontinued Operations* and ASU No. 2014-08, *Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity*. The Company followed the held-for-sale criteria as defined in ASC 205. ASC 205 requires that a component of an entity that has been disposed of or is classified as held for sale and has operations and cash flows that can be clearly distinguished from the rest of the entity be reported as assets held for sale and discontinued operations. In the period a component of an entity has been disposed of, the results of operations for the periods presented are reclassified into separate line items in the consolidated statements of operations. In the period a discontinued operation is classified for sale, the assets and liabilities of the discontinued operation are also reclassified into separate line items on the related consolidated balance sheets for the periods presented.

Due to the sale of the VOWST Business during the third quarter of 2024 (see Note 3, *Discontinued Operations and TSA*), in accordance with ASC 205, *Discontinued Operations*, the Company has classified the results of the VOWST Business as discontinued operations in its consolidated statements of operations and cash flows for all periods presented. All amounts included in the notes to the consolidated financial statements relate to continuing operations unless otherwise noted.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. In these consolidated financial statements, the Company uses estimates and assumptions related to 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.

Restricted Cash

The Company held restricted cash of $8,668 as of December 31, 2025 and 2024, which represents cash held for the benefit of the landlord for certain of the Company's leases. The Company has classified the restricted cash as long-term on its consolidated balance sheets as the underlying leases are greater than 1 year.

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

	December 31,	
	2025	2024
Cash and cash equivalents	$ 45,766	$ 30,793
Restricted cash, non-current	8,668	8,668
Total cash, cash equivalents and restricted cash	$ 54,434	$ 39,461

Concentration of Credit Risk

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

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset, which are as follows:

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

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

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment and right-of-use assets associated with our lease agreements. All of the Company's long-lived assets are to be held and used and have definitive lives and accordingly are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset or asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset or asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. For the years ended December 31, 2025, 2024 and 2023, the Company recorded an impairment loss on long-lived assets of $0, $3,267 and $0, respectively.

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, and beginning in the fourth quarter of 2024 certain costs of fulfilling the Company's obligations under the TSA which are reimbursable by Nestlé.

Research Contract Costs and Accruals

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

Patent Costs

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

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, non-employees, and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options, restricted stock units and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. For stock options or restricted stock units issued with performance-based vesting conditions, the stock compensation expense related to these awards is recognized based on the grant date fair value when achievement of the performance condition is deemed probable.

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

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

The fair value of each stock option grant is estimated on the date of grant using the Black- Scholes option-pricing model. The Company estimates its expected common stock volatility based on its historical common stock volatility for the same time period. The Company uses the simplified method prescribed by Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of options granted to employees, non-employees and directors. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

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 applies ASC 740-10, *Accounting for Uncertain Tax Positions*. The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Segment Reporting

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions, and thus reports as a single reportable segment. The Company's singular focus is on developing live biotherapeutics for medically vulnerable patient populations to prevent bacterial bloodstream and antimicrobial resistant (AMR) infections as well as to treat GI-related immune diseases. 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 Income (Loss)

Comprehensive income (loss) includes net income (loss) as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the year ended December 31, 2023, other comprehensive income consisted of changes in unrealized gains from available-for-sale investments and a currency translation adjustment.

Net Income (Loss) per Share

Basic net income (loss) per share is computed using the weighted average number of common shares outstanding during the period. Diluted net income (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 for periods in which the Company is in a net loss position.

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

Leases

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

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

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

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

Right-of-use assets and lease liabilities are reassessed and remeasured when amendments to the terms of the lease agreement require reassessment and remeasurement of the lease payments and other inputs to the calculation of right-of-use assets and lease liabilities. The Company accounts for remeasurements and modifications to lease liabilities using the present value of remaining lease payments and estimated incremental borrowing rate at the date of remeasurement. The adjustment to the lease liability is recognized as

a gain or loss in operating expenses, or as an adjustment to the right-of-use asset, as appropriate, based on the terms and conditions within the lease that are amended.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as expanded disclosures on income taxes paid by jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard and applied the disclosure requirements on a prospective basis effective for the annual reporting period ended December 31, 2025. There was no impact on the Company's consolidated financial statements and additional required disclosures have been included in Note 11, *Income Taxes*.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses (Topic 220)*, which requires disclosure in the notes to financial statements about specific types of expenses included in the expense captions presented on the face of the statement of operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact related to the adoption of ASU 2024-03 on its financial statement disclosures.

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*, which standardizes the accounting for government grants and distinguishes between a grant related to an asset and a grant related to income. The requirements of the ASU are effective for annual periods beginning after December 15, 2028, and for interim periods within those annual periods, with early adoption permitted. The requirements can be applied using a modified prospective or a modified retrospective approach. The Company does not expect the impact of ASU 2025-10 to be material to its financial statement disclosures as it is consistent with the Company's current accounting policy for government grants.

3. Discontinued Operations and TSA

On September 30, 2024, the Company completed the sale of its VOWST Business to SPN. The Company has determined the sale of the VOWST Business represents a strategic shift that will have a major effect on its business and therefore met the criteria for classification as discontinued operations on September 30, 2024. Accordingly, the VOWST Business is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. The related assets and liabilities of the VOWST Business are classified as assets and liabilities of discontinued operations in the consolidated balance sheets and the results of operations from the VOWST Business as discontinued operations in the consolidated statements of operations. Applicable amounts in prior years have been

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

recast to conform to this discontinued operations presentation. The Company recognized a gain on the sale of the VOWST Business upon closing.

As of December 31, 2025 and 2024, there were no assets or liabilities of discontinued operations.

The following table presents the gain on the sale of the VOWST Business as of December 31, 2024, pursuant to the Purchase Agreement:

	December 31, 2024
Consideration received	
Upfront payment (1)	$ 79,788
Prepaid milestone	60,000
Deferred revenue from termination of 2016 License Agreement	95,364
Settlement of net collaboration payable at close	27,465
Premium on equity financing	1,484
Deferred income from termination of 2021 License Agreement	3,606
Accrued liabilities due to SPN - related party	(33,458)
Total fair value transferred for business	$ 234,249
Net assets transferred	
Inventory	$ 63,442
Prepaid expenses and other current assets	2,219
Property and equipment, net	3,966
Operating lease assets	17,929
Other non-current assets	39,328
Accrued expenses and other current liabilities	(31,547)
Operating lease liabilities	(14,413)
Net assets transferred	$ 80,924
Transaction costs	$ 6,618
Gain on sale, pre-tax	$ 146,707
Income tax	—
Gain on sale, net of tax	$ 146,707

[1] The upfront payment consists of $100,000, less $17,857 owed by the Company to an affiliate of SPN under the prior license agreement between the Company and the SPN affiliate, less approximately $2,355 in satisfaction of costs due under the Bacthera Manufacturing Agreement.

For the year ended December 31, 2024, the gain from sale of the VOWST Business, net of tax of $146,707 was included in the net income (loss) from discontinued operations, net of tax line item of the Company's consolidated statements of operations and comprehensive income (loss). While the Company has net income from discontinued operations for the year ended December 31, 2024, the Company realized a tax loss for the full year ended December 31, 2024, for which it is more likely than not that the Company will not realize a benefit. The Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2025, 2024 and 2023.

The following table presents the financial results of the discontinued operations:

	Year Ended December 31,		
	2025	2024	2023
Revenue:			
Collaboration revenue - related party	$ —	$ —	$ 126,325
Total revenue	—	—	126,325
Operating expenses:			
Research and development expenses	—	5,809	28,263
General and administrative expenses	—	4,066	10,244
Collaboration (profit) loss sharing - related party	—	(1,496)	704
Total operating expenses	—	8,379	39,211
(Loss) income from discontinued operations	—	(8,379)	87,114
Other income (expense):			
Gain on sale of VOWST business	—	146,707	—
Interest expense	—	(12,192)	(10,708)
Other expense	—	(229)	—
Income (loss) from discontinued operations, pre-tax	$ —	$ 125,907	$ 76,406
Income tax	—	—	—
Net income (loss) from discontinued operations, net of tax	$ —	$ 125,907	$ 76,406

In accordance with ASC 205-20, only expenses specifically identifiable and related to a business to be disposed may be presented in discontinued operations. As such, the research and development and general and administrative expenses in discontinued operations include corporate costs incurred directly to solely support the VOWST Business.

The Company also entered into a Transition Services Agreement ("TSA") with NESA, an affiliate of SPN, in connection with the Transaction, through which the Company provided certain manufacturing services until December 31, 2025, and other transition services, for the duration specified in the schedule to the TSA for each service. For the years ended December 31, 2025 and 2024, the Company recognized $13,311 and $6,292 of TSA reimbursement income in other income in the Company's consolidated statements of operations and comprehensive income. For the years ended December 31, 2025 and 2024, the Company incurred $6,544 and $3,532 of expenses related to manufacturing services and $3,592 and $3,136 of TSA labor and passthrough expenses to support the transition services, including finance and accounting, information technology, human resources, operations, and other services.

For the years ended December 31, 2025 and 2024, $14,897 and $3,724 was billed to NESA related to transition services performed by the Company, and the Company received $91,605 and $1,656 from NESA during the periods including the first installment payment of $50,000 received in January 2025 and the second installment payment of $25,000 received in July 2025 which were conditioned on the Company's material compliance with obligations under the TSA. The $75,000 of installment payments were recognized in Gain on sale of VOWST Business within continuing operations in the Company's consolidated statements of operations and comprehensive income for the year ended December 31, 2025 as the gain was realizable. As of December 31, 2025 and 2024, the Company had $360 and $2,068 in accounts receivable due from SPN - related party in the Company's consolidated balance sheets.

The Company has estimated costs associated with certain accrued liabilities due to SPN - related party as a loss contingency in accordance with ASC 450, *Contingencies.* These contingent liabilities are presented as Accrued Liabilities due to SPN - related party from continuing operations on the consolidated balance sheets as of December 31, 2025 and December 31, 2024 and consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Profit Sharing Payments	$ 1,701	$ 11,230
Royalties associated with the MSK Agreement	1,309	2,786
VOWST post-marketing safety surveillance study	268	771
80.1% of lease cost of Waltham facility	—	1,501
Employment-related costs for conveying employees	—	1,462
Total accrued liabilities due to SPN - related party	$ 3,278	$ 17,750

The contingent liabilities accrued on the Company's consolidated balance sheets are remeasured at December 31, 2025 based on i) cash payments made by the Company to reduce the accrued liabilities due to SPN - related party and ii) revised estimates of the total remaining liabilities due to SPN - related party. For the years ended December 31, 2025 and 2024, the Company recognized a gain

on sale of VOWST Business of $5,685 and $5,684, respectively, as a result of the change in the accrued liabilities due to SPN - related party.

The Company has excluded from its consolidated balance sheets the effects of certain milestone payments received by the Company after the Product has achieved net sales-based milestones. These contingent receivables will be recognized as a gain contingency, in accordance with *ASC 450, Contingencies,* in continuing operations in the period when the contingencies are resolved.

The cash flows related to discontinued operations have not been segregated and are included in the consolidated statements of cash flows. There were no cash flows related to discontinued operations for the year ended December 31, 2025. For the years ended December 31, 2024 and 2023, capital expenditures related to the VOWST Business were $112 and $2,272, respectively. Depreciation expense related to the VOWST Business for the same periods was $989 and $2,019, respectively. Non-cash operating lease costs related to the VOWST Business for the years ended December 31, 2024 and 2023 were $1,447 and $2,123, respectively, while the share based compensation expense for the same periods were $1,884 and $2,773, respectively. The collaboration loss sharing (related party) related to the VOWST Business was $0 and $5,158 for the years ended December 31, 2024 and 2023, respectively. Excluding the gain of $146,707 recognized on the sale of the VOWST Business presented in the consolidated statements of cash flows for the year ended December 31, 2024, there were no other material operating or investing non-cash items related to the VOWST Business for any period presented.

4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2025	2024
Laboratory equipment	$ 23,852	$ 24,468
Computer equipment	4,058	3,924
Furniture and office equipment	4,523	4,523
Leasehold improvements	30,954	30,954
Construction in progress	861	861
	64,248	64,730
Less: Accumulated depreciation and amortization	(56,613)	(53,196)
	$ 7,635	$ 11,534

Depreciation and amortization expense was $4,133, $5,468 and $6,243 for the years ended December 31, 2025, 2024 and 2023, respectively, which includes amounts related to both continuing and discontinued operations. During the years ended December 31, 2025 and 2024, the Company disposed of certain assets with a cost basis of $734 and $679, respectively, and a net book value of $18 and $0, respectively. In addition, during the year ended December 31, 2024, the Company recorded an impairment loss of $1,536 related to leasehold improvements at one of the Company's locations for which impairment indicators were determined to exist as of December 31, 2024. See Note 6, *Leases*, for further details.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2025	2024
Clinical and development costs	$ 246	$ 422
Manufacturing and quality costs	145	478
Payroll and employee-related costs	2,685	7,656
Facility and other	896	2,163
	$ 3,972	$ 10,719

6. Leases

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

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

During the year ended December 31, 2024, the Company identified an indicator of impairment of its donor collection facility in Cambridge, Massachusetts, as the facility is no longer being used by the Company and is being marketed for sublease. The Company determined that this represents a significant adverse change in the extent in which the long-lived asset was being used. The Company determined that the location contains multiple asset groups for the purpose of the long-lived asset impairment assessment. The Company concluded that the carrying value of each asset group was not recoverable as it exceeded the future net undiscounted cash flows that are expected to be generated from the assets within the asset group. In the first quarter of 2024, the Company recognized an impairment loss of $3,267, consisting of $1,731 on the operating lease right-of-use asset and $1,536 on the leasehold improvements. $2,727 of the total impairment loss is included in research and development expenses and the remaining $540 is included in general and administrative expenses in the accompanying consolidated statements of operations and comprehensive income (loss).

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

	December 31,	
	2025	2024
Assets:		
Operating lease assets	$ 72,483	$ 80,903
Liabilities:		
Operating lease liabilities	$ 10,390	$ 8,674
Operating lease liabilities, net of current portion	72,576	82,966
Total operating lease liabilities	$ 82,966	$ 91,640

The following table summarizes the effect of lease costs in the Company's consolidated statements of operations and comprehensive income (loss) (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Operating lease costs	$ 19,175	$ 19,514	$ 22,324
Short-term lease costs	—	—	1,477
Variable lease costs	6,467	6,589	7,229
Sublease income	(3,272)	(2,708)	—
Total lease costs	$ 22,370	$ 23,395	$ 31,030

During the years ended December 31, 2025, 2024, and 2023, the Company made cash payments for operating leases of $19,442, $17,330 and $15,656, respectively.

As of December 31, 2025, future payments of operating lease liabilities are as follows (in thousands):

	As of December 31, 2025
2026	$ 19,983
2027	20,582
2028	20,863
2029	20,132
2030	11,545
2031 and thereafter	25,317
Total future payments of operating lease liabilities	$ 118,422
Less: imputed interest	(35,456)
Present value of operating lease liabilities	$ 82,966

As of December 31, 2025, the weighted average remaining lease term was 6.07 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%. As of December 31, 2024, the weighted average remaining lease term was 6.98 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%.

7. Stock and Stock-Based Awards

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.

On April 10, 2025, at the Company's 2025 annual meeting of stockholders (the "2025 Annual Meeting"), stockholders approved an amendment to the Company's Restated Certificate of Incorporation in order to effect a reverse stock split of all outstanding shares of the Company's common stock. On April 21, 2025, the Company effected a 1-for-20 reverse stock split of its common stock. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. As of the effective time of the reverse stock split, the number of shares of common stock issuable upon exercise, vesting or settlement of outstanding awards, the exercise price of all outstanding options and any stock price vesting goals with respect to any outstanding awards under the Company's equity plans (including the 2025 Plan, as defined below) was proportionately adjusted (and rounded down to the nearest whole share in the case of shares and up to the nearest whole cent in the case of exercise prices, as applicable) based on the 1-for-20 ratio. In addition, the number of shares available for future issuance and any share-based award limits under the Company's equity plans were proportionately reduced based on the 1-for-20 ratio. Trading of the Company's common stock on The Nasdaq Global Select Market commenced on a split-adjusted basis on April 22, 2025.

On September 30, 2024, the Company entered into the Securities Purchase Agreement with SPN, pursuant to which SPN purchased 714,285 shares at the Closing at a purchase price per share of $21.00, for an aggregate purchase price of $15,000. Under the terms of the Securities Purchase Agreement, SPN has agreed not to sell or transfer the shares for a period of six months after Closing, subject to certain customary exceptions. The Company agreed to register the resale of the Shares by SPN within 90 days of Closing. On October 1, 2024, the Company filed a registration statement to register the Shares, which became effective on October 11, 2024. In addition, under the terms of the Securities Purchase Agreement, for as long as SPN, together with its affiliates, beneficially owns at least 10% of the Company's outstanding shares of common stock, the Company has agreed to take such action within its control to include one individual designated by SPN in the slate of nominees recommended by the Company's board of directors (or the applicable committee of the board) to the Company's stockholders for election to the board at the applicable stockholder meeting. The Securities Purchase Agreement contains customary representations and warranties and closing conditions. The aggregate fair value of $13,516 for the common stock issued to SPN was recorded in equity, with the remaining $1,484 cash received from SPN under the Securities Purchase Agreement allocated to the consideration transferred for the VOWST Business.

On February 22, 2024, the Company's board of directors adopted a resolution to amend the Restated Certificate of Incorporation, subject to stockholder approval, by increasing the number of authorized shares of the Company's Common Stock from 240,000,000 shares to 360,000,000 shares (the "Share Increase Amendment"). At the Company's annual meeting of stockholders held on April 4, 2024, the Company's stockholders approved the Share Increase Amendment. On April 5, 2024, the Company amended its Restated Certificate of Incorporation to reflect the Share Increase Amendment.

In May 2021, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to $150,000, from time to time, through an "at-the-market" equity offering program ("ATM") under which Cowen acts as sales agent. During the year ended

December 31, 2025, the Company sold 739,545 shares of common stock under the 2021 Sales Agreement, at an average price of approximately $18.48 per share, raising aggregate net proceeds of approximately $13,167 after deducting an aggregate commission of approximately 3% and other issuance costs. During the year ended December 31, 2024, the Company sold 1,030,846 shares of common stock under the 2021 Sales Agreement, at an average price of approximately $23.67 per share, raising aggregate net proceeds of approximately $23,530 after deducting an aggregate commission of approximately 3% and other issuance costs.

2015 and 2025 Incentive Award Plans

On June 16, 2015, the Company's stockholders approved the 2015 Incentive Award Plan (the "2015 Plan"), which became effective on June 25, 2015. The 2015 Plan was subsequently amended on December 14, 2022, and provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares initially reserved for issuance under the 2015 Plan was the sum of (i) 110,000 shares of common stock and (ii) the number of shares subject to awards outstanding under the 2012 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company on or after the effective date of the 2015 Plan. In addition, the number of shares of common stock that may be issued under the 2015 Plan was 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.

On April 10, 2025, the Company's stockholders approved the 2025 Incentive Award Plan (the "2025 Plan") as an amendment and restatement of the Seres Therapeutics, Inc. 2015 Incentive Award Plan. The amendment, among other things, authorized the issuance of 2,230,243 shares of the Company's common stock for awards under the 2025 Plan, which includes 1,750,493 shares previously authorized for issuance under the 2015 Plan plus an increase of 479,750 shares (in each case, which amounts reflect the 1-for-20 reverse stock split), and extended the term of the 2025 Plan to March 3, 2035, the tenth anniversary of the approval of the 2025 Plan by the Company's board of directors.

Stock awards granted under the 2025 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, 2025, there were 740,410 shares available for future grant under the 2025 Plan.

2015 Employee Stock Purchase Plan

On June 16, 2015, the Company's stockholders approved the 2015 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 25, 2015. A total of 18,250 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) 20,000 shares, (ii) 1% of the number of shares of the Company's common stock outstanding on the last day of the applicable preceding calendar year and (iii) an amount determined by the Company's board of directors. Offering periods under the ESPP will commence when determined by the plan administrator. During the year ended and as of December 31, 2025, there were 17,839 shares issued and 106,064 shares were reserved and available for issuance under the ESPP, respectively.

The ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock. Purchase rights issued under the ESPP are intended to be qualified under Section 423 of the Internal Revenue Code of 1986, as amended ("IRC"). The employee's purchase price is derived from a formula based on the closing price of the common stock on the first day of the offering period versus the closing price on the date of purchase (or, if not a trading day, on the immediately preceding trading day). The offering period under the ESPP has a duration of six months, and the purchase price with respect to each offering period beginning on or after such date is, until otherwise amended, equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month offering period or (ii) the fair market value of the Company's common stock on the purchase date.

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

2022 Employment Inducement Award Plan

On December 14, 2022, the Company's board of directors approved the 2022 Employment Inducement Award Plan (the "2022 Plan"), which became effective on such date without stockholder approval pursuant to Rule 5635(c)(4) of The Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)"). The 2022 Plan provides for the grant of nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock- or cash-based awards. In accordance with Rule 5635(c)(4), awards under the 2022 Plan may only be made to a newly hired employee who has not previously been a member of our board of directors, or an employee who is being rehired following a bona fide period of non-employment by us as a material inducement to the employee's entering into employment with us. A total of 125,000 shares of common stock were reserved for issuance under the 2022 Plan. Any shares subject to awards previously granted under the 2022 Plan that expire, terminate or are otherwise surrendered, canceled, or forfeited in any case, in a manner that results in the Company acquiring the shares covered by the award at a price not greater than the price (as adjusted to reflect any equity restructuring) paid by the Participant for such shares or not issuing any shares covered by the award, the unused shares covered by the award will again be available for award grants under the 2022 Plan.

As of December 31, 2025, there were 86,644 shares available for future grant under the 2022 Plan.

Stock Options

The following table summarizes the Company's stock option activity for the year ended December 31, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	886,123	$ 114.47	6.59	$ 87
Granted	546,805	$ 15.14		
Exercised	(23,900)	$ 20.96		
Forfeited	(284,820)	$ 114.77		
Outstanding as of December 31, 2025	1,124,208	$ 68.07	7.17	$ 228
Vested and expected to vest as of December 31, 2025	1,124,208	$ 68.07	7.17	$ 228
Options exercisable as of December 31, 2025	502,733	$ 129.06	5.15	$ 31

In February 2024, the Company approved a repricing of certain stock option awards to reduce the original exercise price to the Company's current fair market value as of February 12, 2024 (the "Repricing"). The Repricing became effective 18 months from the approval date, or August 2025. The remaining terms and conditions of each option affected by the Repricing remained the same, including the expiration date, vesting commencement date, vesting schedule and any vesting acceleration. As the Repricing was retrospective to February 2024, the weighted average exercise price for stock options outstanding as of December 31, 2024 in the table above has been adjusted to reflect the Repricing. The Repricing was accounted for as a modification, and an immaterial amount of incremental fair value is being recognized from the date the Repricing was approved over the remaining vesting term of the options.

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2025, 2024, and 2023 was $13.30, $18.58, and $90.37 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2025, 2024, and 2023 was $98, $0, and $438, respectively.

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

During the year ended December 31, 2021, the Company granted performance-based stock options to employees for the purchase of an aggregate of 28,100 shares of common stock with a grant date fair value of $110.60 per share. These stock options are exercisable only upon achievement of specified performance targets. In April 2023, the performance target associated with 50% of the performance-based stock options was achieved. Accordingly, the Company recorded $0, $8 and $2,051 of compensation expense during the years ended December 31, 2025, 2024 and 2023, respectively, with respect to these performance-based stock options, which represents a cumulative catch-up from the grant date through the achievement of the performance targets, and vesting of the remaining 50% of the options beginning in April 2023. The remaining compensation expense associated with these performance-based stock options was recognized as of April 2024, for all such options for which ongoing performance targets were achieved and service requirements were met.

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

During the three months ended March 31, 2024, the Company granted stock options to certain executives for the purchase of an aggregate of 127,500 shares of common stock. These awards will vest only to the extent that the 30-day trailing simple average public market closing price of the Company's common stock reaches certain price thresholds. These awards have an exercise price of $22.00 and vest and become exercisable when the market conditions are satisfied or, if later, on the first anniversary of the grant date. These awards expire 10 years from the date of grant. The fair value of these market-based stock options was estimated using a Monte Carlo valuation method. During the years ended December 31, 2025 and 2024, the Company recognized $641 and $775 of compensation expense related to these awards.

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions ("RSUs") and restricted stock units with performance-based vesting conditions ("PSUs"). RSUs and PSUs represent the right to receive shares of common stock upon meeting specified vesting requirements. Restricted stock units may not be sold or transferred by the holder and vest according to the vesting conditions of each award. The table below summarizes the Company's RSU and PSU activity for the year ended December 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2024	81,459	$ 55.36
Granted	79,846	$ 18.29
Forfeited	(12,300)	$ 62.76
Vested	(124,855)	$ 30.54
Unvested restricted stock units as of December 31, 2025	24,150	$ 57.31

During the years ended December 31, 2025, 2024, and 2023, the Company granted 79,846, 75,066 and 154,904 RSUs, respectively. RSUs generally vest over four years, with 25% vesting after one year, and the remaining 75% vesting quarterly over the next 3 years, subject to continued service to the Company through the applicable vesting date. PSUs vest according to the performance requirements of the awards, generally when the Company has determined that the specified performance targets have been achieved.

During the year ended December 31, 2023, the Company granted PSUs to employees covering an aggregate of 66,135 shares of common stock with a grant date fair value of $110.00. These PSUs begin to vest ratably only upon achievement of specified performance targets, which were achieved in April 2023. Accordingly, the Company recorded $0, $792 and $4,293 in compensation expense during the years ended December 31, 2025, 2024, and 2023 respectively, with respect to these PSUs.

The aggregate intrinsic value of RSUs, including PSUs for which the performance conditions have been met, that vested during the years ended December 31, 2025, 2024 and 2023 was $1,903, $1,899, and $4,729, respectively.

Retention Awards

In September 2025, the Company issued retention awards to employees of the Company in the form of RSUs covering 68,596 shares of common stock with a grant date fair value of $18.93 per share. The retention RSUs fully vested on November 15, 2025 subject to the employee's continued employment with the Company through such date. The compensation expense associated with these awards was recognized ratably over the vesting period. For the year ended December 31, 2025, the Company recognized $1,299 in compensation expense with respect to the retention RSUs.

In November 2023, as part of the corporate restructuring described in Note 9, *Restructuring*, the Company issued retention awards to employees of the Company in the form of RSUs, which vested as to the first tranche on August 15, 2024 and as to the second tranche on May 15, 2025, subject to remaining actively employed with the Company through such date. The compensation expense associated with these awards was recognized ratably over the vesting period. For the years ended December 31, 2025, 2024, and 2023, the Company recognized $163, $655 and $92, respectively, in compensation expense with respect to the retention awards.

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

Stock-based Compensation Valuation

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

	Year Ended December 31,		
	2025	2024	2023
Risk-free interest rate	4.26%	2.70%	3.64%
Expected term (in years)	6.0	6.0	6.0
Expected volatility	121.0%	76.2%	107.2%
Expected dividend yield	0%	0%	0%

The Company estimates the fair value of rights to acquire common stock under the ESPP using a Black-Scholes valuation model on the date of grant and the straight-line attribution approach to recognize the expense. The assumptions that the Company used to determine the fair value of rights to acquire common stock under the ESPP were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2025	2024	2023
Risk-free interest rate	4.34%	5.16%	5.01%
Expected term (in years)	0.5	0.5	0.5
Expected volatility	115.8%	118.3%	79.1%
Expected dividend yield	0%	0%	0%

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted stock units in the following expense categories of its consolidated statements of operations and comprehensive income (loss):

	Year Ended December 31,		
	2025	2024	2023
Research and development expenses	$ 5,080	$ 10,996	$ 19,341
General and administrative expenses	5,760	9,975	14,760
	$ 10,840	$ 20,971	$ 34,101

As of December 31, 2025, the Company had an aggregate of $9,986 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.2 years.

8. Net Income (Loss) per Share

Basic and diluted net income (loss) per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Year Ended December 31,		
	2025	2024	2023
Basic Earnings Per Share:			
Numerator:			
Net income (loss) from continuing operations attributable to common stockholders	$ 5,696	$ (125,771)	$ (190,130)
Net income from discontinuing operations attributable to common stockholders	$ —	$ 125,907	$ 76,406
Net income (loss) attributable to common stockholders	$ 5,696	$ 136	$ (113,724)
Denominator:			
Weighted average common shares outstanding - basic	8,858,975	7,769,910	6,400,339
Net income (loss) from continuing operations per share attributable to common stockholders - basic	$ 0.64	$ (16.20)	$ (29.71)
Net income from discontinued operations per share attributable to common stockholders - basic	$ —	$ 16.20	$ 11.94
Net income (loss) per share attributable to common stockholders - basic	$ 0.64	$ 0.00	$ (17.77)
Diluted Earnings Per Share:			
Numerator:			
Net income (loss) from continuing operations attributable to common stockholders	$ 5,696	$ (125,771)	$ (190,130)
Net income from discontinuing operations attributable to common stockholders	$ —	$ 125,907	$ 76,406
Net income (loss) attributable to common stockholders	$ 5,696	$ 136	$ (113,724)
Denominator:			
Weighted average common shares outstanding - basic	8,858,975	7,769,910	6,400,339
Dilutive impact from:			
Stock options to purchase common stock	—	—	—
Unvested restricted stock units	10,749	—	—
Shares issuable under employee stock purchase plan	18	—	—
Weighted average common shares outstanding - diluted	8,869,742	7,769,910	6,400,339
Net income (loss) from continuing operations per share attributable to common stockholders - diluted	$ 0.64	$ (16.20)	$ (29.71)
Net income from discontinued operations per share attributable to common stockholders - diluted	$ —	$ 16.20	$ 11.94
Net income (loss) per share attributable to common stockholders - diluted	$ 0.64	$ —	$ (17.77)
Anti-dilutive potential common stock equivalents excluded from the calculation of net income (loss) per share:			
Stock options to purchase common stock	1,124,208	886,123	742,335
Unvested restricted stock units	24,150	81,459	168,730
Shares issuable under employee stock purchase plan	2,047	7,160	14,889
Warrants to purchase common stock	32,379	32,379	58,871

The Company's potential dilutive securities include stock options, unvested restricted common stock and shares issuable under the 2015 Employee Stock Purchase Plan. The effect of dilutive securities was calculated using the treasury stock method. The anti-dilutive potential common stock equivalents for the year ended December 31, 2025 were excluded from the computation of diluted net income per share attributable to common stockholders because those stock options to purchase common stock and restricted stock units had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those periods. For that same period, the warrants to purchase common stock were excluded because the exercise price of the Tranche A Warrants is greater than the average fair value of the Company's common shares. The anti-dilutive potential common stock equivalents for the years ended December 31, 2024 and 2023 were excluded from the computation of diluted net loss per share attributable to common stockholders because those stock options to purchase common stock, restricted stock units, and shares issuable under employee stock purchase plan had an anti-dilutive impact as the Company reported a net loss from continuing operations attributable to common stockholders for those periods

The Company utilizes the control number concept in the computation of diluted earnings per share to determine whether potential common stock equivalents are dilutive. The control number used is income (loss) from continuing operations. The control number concept requires that the same number of potentially dilutive securities applied in computing diluted earnings per share from continuing operations be applied to all other categories of income or loss, regardless of their anti-dilutive effect on such categories. Since the Company had a net loss from continuing operations for all periods in which discontinued operations is presented, no dilutive effect has been recognized in the calculation of income from discontinued operations 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 for the years ended December 31, 2024 and 2023.

9. Restructuring

On September 23, 2025, the Company announced that it implemented cost reduction actions, including decreasing its workforce by approximately 25%. During the year ended December 31, 2025, the Company incurred approximately $1,027 in restructuring costs, primarily related to severance costs. These costs were paid out in the fourth quarter of 2025.

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

During the year ended December 31, 2023, the Company recognized a restructuring charge of $5,606, which was incurred entirely in the fourth quarter of 2023, and which represents all restructuring charges expected to be incurred. $3,481 of the total restructuring charges was included in research and development expenses and the remaining $2,125 in general and administrative expenses in the accompanying consolidated statements of operations and comprehensive income (loss) for the year ended December 31, 2023. Restructuring charges included approximately $5,345 of employee related termination costs in the form of salary continuation and cash severance payments, and $261 related to the acceleration of vesting of certain previously granted RSUs and PSUs.

The unpaid restructuring charge included in accrued expenses and other current liabilities in the Company's consolidated balance sheets was $0 and $20 for the years ended December 31, 2025 and 2024, respectively.

10. Commitments and Contingencies

Leases

Refer to Note 6, *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

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

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, 2025 or 2024.

Legal Contingencies

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities would be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

The Company did not accrue any liabilities related to legal contingencies in its consolidated financial statements as of December 31, 2025 or 2024.

11. Income Taxes

During the years ended December 31, 2025, 2024 and 2023, 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 after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2025	
	Amount	%
Federal statutory income tax rate	$ 1,202	21.0%
State and local income taxes, net of federal income tax effect[1]	—	—%
Tax credits		
Research and development tax credits	334	5.8%
Changes in valuation allowance	(3,445)	(60.2)%
Nontaxable or nondeductible items		
Meals and entertainment	14	0.3%
Stock-based compensation	3,094	54.1%
Adjustment to gain on sale of VOWST business	(1,133)	(19.8)%
Changes in unrecognized tax benefits	(67)	(1.2)%
Other adjustments	1	0.0%
Effective income tax rate	$ —	—%

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

[1] State and local taxes in Massachusetts comprise the majority of this category.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for years prior to the adoption of ASU 2023-09 is as follows:

	Year Ended December 31,	
	2024	2023
Federal statutory income tax rate	(21.0)%	(21.0)%
Research and development tax credits	(1.8)	(2.5)
State taxes, net of federal benefit	(3.6)	(7.2)
Stock-based compensation	1.0	0.8
Uncertain tax position reserves	0.4	0.5
Other	(0.4)	(0.1)
Change in deferred tax asset valuation allowance	25.4	29.5
Effective income tax rate	—%	—%

Net deferred tax assets as of December 31, 2025 and 2024 consisted of the following:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 167,203	$ 156,157
Research and development tax credit carryforwards	54,149	54,648
Section 174 capitalized research and development expenses	39,759	53,600
Stock-based compensation expense	28,594	28,819
Lease liability	22,689	23,917
Contingent consideration	13,437	—
Accrued expenses	1,788	7,032
Section 163(j) limitation	1,843	5,599
Depreciation and amortization	1,223	953
Other	98	132
Total deferred tax assets	$ 330,783	$ 330,857
Deferred tax liabilities:		
Depreciation and amortization	—	—
Right of use assets	(19,822)	(21,115)
Total deferred tax liabilities	(19,822)	(21,115)
Valuation allowance	$ (310,961)	$ (309,742)
Net deferred tax assets	$ —	$ —

The Tax Cuts and Jobs Act ("TCJA"), which was enacted in 2017, required taxpayers to capitalize and amortize research and experimental expenditures under IRC Section 174 for tax years beginning after December 31, 2021. This rule became effective for the Company during the year ended December 31, 2022 and resulted in the capitalization of research and development costs for the years ended December 31, 2024, 2023, and 2022. The TCJA required the Company to amortize these costs for tax purposes over five years if the research and development was performed in the U.S. and over 15 years if the research and development was performed outside the U.S. On July 4, 2025, new U.S. tax legislation was signed into law (known as the "One Big Beautiful Bill Act", or "OBBA") which generally allows taxpayers to (i) immediately deduct research and experimental expenditures attributable to U.S.-based research paid or incurred in taxable years beginning after December 31, 2024 and (ii) elect to accelerate, over a period of one or two years, any unamortized research and experimental expenditures attributable to U.S.-based research incurred in taxable years beginning after December 31, 2021 and before January 1, 2025. The Company deducted 100% of its research and experimental expenditures incurred in 2025 during the year ended December 31, 2025. Further, the Company has elected not to accelerate the unamortized research and experimental expenditures from prior years and instead recognize them over the remaining amortization period of five years from when they were initially capitalized.

For the year ended December 31, 2025, the Company did not have any material cash payments or refunds for income taxes.

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

As of December 31, 2025, the Company had net operating loss carryforwards ("NOLs") for federal and state income tax purposes of $616,412 and $597,758, respectively. Federal NOLs of $98,756, generated before 2018, will begin expiring in varying amounts in 2035 unless utilized. The remaining federal NOLs of $517,656, generated after 2017, will be carried forward indefinitely and could be used to offset up to 80% of taxable income in future tax years. The Company's state NOLs will expire at various times starting in 2035. As of December 31, 2025, the Company also had available gross research and development tax credit carryforwards for federal and state income tax purposes of $55,341 and $14,767, respectively, which begin to expire in 2031 and 2028, respectively. The federal research and development tax credits include an orphan drug credit carryforward of $25,876.

Utilization of the NOLs and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the IRC due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in an ownership change or could result in an ownership change in the future upon subsequent disposition. The Company conducted an analysis to determine if historical changes in ownership through December 31, 2024 would limit or otherwise restrict its ability to utilize these NOLs and research and development credit carryforwards. As a result of this analysis, the Company does not believe there are any significant limitations on its ability to utilize these carryforwards. However, future changes in ownership after December 31, 2024 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, 2025 and 2024. 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, 2025, 2024 and 2023 related primarily to the increases or decreases in NOLs, research and development tax credit carryforwards, capitalized research and development expenses pursuant to IRC Section 174, and non-deductible stock-based compensation expenses. A rollforward of the valuation allowance is as follows:

	Year Ended December 31,		
	2025	2024	2023
Valuation allowance at beginning of year	$ (309,742)	$ (312,809)	$ (277,370)
Decreases recorded as benefit to income tax provision		3,067	—
Increases recorded to income tax provision	(1,219)	—	(35,439)
Valuation allowance as of end of year	$ (310,961)	$ (309,742)	$ (312,809)

During the year ended December 31, 2023, the Internal Revenue Service ("IRS") concluded their examination of the Company for the period ended December 31, 2018 related to the Company's 2018 research and development tax credits ("R&D Credit(s)"). The Company has adjusted its 2018 R&D Credits and its overall federal and state R&D Credit carryforward balance from the Company's inception to December 31, 2025 to account for the conclusions drawn by the IRS. Also, the Company has reviewed each of its overall filing positions since inception and has not identified any additional positions that do not meet the more likely than not threshold. The Company does not anticipate a material change to its uncertain tax position reserves in the next 12 months. The changes in the Company's unrecognized tax benefits for the years ended December 31, 2025, 2024, and 2023 were as follows:

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

	Year Ended December 31,		
	2025	2024	2023
Balance at beginning of year	$ 14,015	$ 13,529	$ 12,528
Increase in unrecognized tax benefits as a result of tax positions taken during the year	129	486	1,001
(Decrease) in unrecognized tax benefits as a result of tax positions taken during the year	(289)	—	—
Reduction to unrecognized tax benefits	—	—	—
Balance at end of year	$ 13,855	$ 14,015	$ 13,529

The Company has not yet conducted a study of its research and development credit carry forwards. This study may result in further adjustment to the Company's R&D Credits; however, a full valuation allowance has been provided against the Company's R&D Credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheets or statements of operations if an adjustment were required. The Company had no other unrecognized tax benefits accrued for the years ended December 31, 2025 and 2024, or related interest and penalties as of such dates. The Company will recognize any interest and penalties related to uncertain tax positions in income tax expense.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company's tax years are still open under statute from 2011 to present. All years may be examined to the extent the tax credit or net operating loss carryforwards are used in future periods.

12. Related Party Transactions

As described in Note 1, *Nature of the Business and Basis of Presentation* and Note 3, *Discontinued Operations*, in September 2024, the Company sold the VOWST Business, including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of VOWST, to SPN, and SPN assumed certain liabilities from the Company. As consideration for the Transaction, the Company received an upfront cash payment of $139,788, which consists of $100,000, less $17,857 owed by the Company to an affiliate of SPN under the prior license agreement between the Company and the SPN affiliate, less approximately $2,355 in satisfaction of fees due under the Bacthera Manufacturing Agreement; plus a prepayment of the $60,000 milestone payment tied to the achievement of worldwide annual net sales of VOWST of $150,000; plus an equity investment of $15,000 based on the Securities Purchase Agreement pursuant to which SPN purchased 714,285 shares of common stock at a purchase price of $21.00 per share.

For the years ended December 31, 2025 and 2024, the Accrued Liabilities due to SPN - related party on the Company's consolidated balance sheets were $3,278 and $17,750, respectively, which represents amounts due to SPN pursuant to the Purchase Agreement, which are further described in Note 3, *Discontinued Operations and TSA*. During the years ended December 31, 2025 and 2024, the Company paid $8,787 and $9,608, respectively, related to the outstanding liability. The Company also recognized a gain on sale of VOWST Business of $5,685 and $5,684, for the years ended December 31, 2025 and 2024, respectively, as a result of the change in the accrued liabilities due to SPN - related party, primarily as a result of SPN's actual Profit Sharing Payments as compared to the estimate as of the Closing.

As described in Note 3, *Discontinued Operations and TSA*, the Company entered into the TSA with NESA, an affiliate of SPN, in connection with the Transaction, through which the Company provided certain manufacturing services until December 31, 2025, and other transition services, for the duration specified in the schedule to the TSA for each service. For the years ended December 31, 2025 and 2024, the Company recognized $13,311 and $6,292 of TSA reimbursement income in other (expense) income, net in the Company's consolidated statements of operations and comprehensive income (loss). For the years ended December 31, 2025 and 2024, the Company incurred $6,544 and $3,532 of expenses related to manufacturing services and $3,592 and $3,136 of TSA labor and passthrough expenses to support the transition services, including finance and accounting, information technology, human resources, operations, and other services.

For the years ended December 31, 2025 and 2024, $14,897 and $3,724 was billed to NESA related to transition services performed by the Company, and the Company received $91,605 and $1,656 from NESA during the periods including the first installment payment of $50,000 received in January 2025 and the second installment payment of $25,000 received in July 2025 which were

conditioned on the Company's material compliance with obligations under the TSA. The $75,000 of installment payments were recognized in Gain on sale of VOWST Business within continuing operations in the Company's consolidated statements of operation and comprehensive income for the year ended December 31, 2025 as the gain was realizable. As of December 31, 2025, the Company had $360 in accounts receivable due from SPN - related party in the Company's consolidated balance sheets.

For the year ended December 31, 2025, Nestlé purchase certain manufacturing and laboratory equipment from the Company. The Company received $169 in proceeds from the sale, which is recognized in Other income (expense), net in the Company's consolidated statements of operations and comprehensive income (loss).

13. 401(k) Savings Plan

The Company has a defined contribution savings plan under Section 401(k) of the IRC. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Effective January 1, 2016, the Company elected to match 50% of the first 6% of an employee's deferral. Company contributions are expensed in the year for which they are declared. During the years ended December 31, 2025, 2024, and 2023 the Company recorded expense of $592, $1,068, and $2,003, respectively, for 401(k) match contributions.

14. Segment Reporting

The Company's interim Chief Executive Officer, who is the Chief Operating Decision Maker ("CODM"), manages and allocates resources to the operations of the Company on a total company basis by assessing the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with the Company's long-term company-wide strategic goals. The CODM uses the Company's consolidated net income (loss) to monitor actual results versus the budget in assessing segment performance and the allocation of resources. The measure of segment assets is reported on the consolidated balance sheets as total assets.

The Company's reportable segment net income (loss) for the years ended December 31, 2025, 2024 and 2023, consisted of the following (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Grant revenue	$ 789	$ —	$ —
Significant segment expenses:			
Live biotherapeutics platform	$ 23,573	$ 29,006	$ 43,342
SER-155	3,687	6,804	7,759
R&D personnel-related (including stock-based compensation)	21,553	28,689	65,251
G&A personnel-related (including stock-based compensation)	14,413	22,679	36,069
Professional fees	8,991	9,805	18,784
Facility-related and other	15,752	20,699	22,647
Gain on sale of VOWST Business	(80,685)	(5,684)	-
Other segment (income) expense (1)	(12,191)	13,773	(3,722)
Net income (loss) from continuing operations	5,696	(125,771)	(190,130)
Net income from discontinued operations, net of tax (2)	—	125,907	76,406
Net income (loss)	$ 5,696	$ 136	$ (113,724)

[1] Other segment (income) expense includes manufacturing services expenses, research and development expenses on early stage programs, interest income and other (income) expense, net.

[2] See Note 3, *Discontinued Operations and TSA*, for further details.

15. Subsequent Events

Executive Officer Transition

On February 27, 2026, the Board of Directors (the "Board") of the Company appointed Richard N. Kender, a current member of the Board, to serve as Executive Chair of the Board and as Interim Chief Executive Officer of the Company, Matthew Henn, Ph.D., the Company's Chief Scientific Officer, to the additional role of President, and Kelly Brady, M.S., the Company's Senior Vice President, Clinical Development, to the role of Executive Vice President, Chief Operating Officer, each effective March 2, 2026 (the "Effective Date").

As a result of the appointment of Mr. Kender as Interim Chief Executive Officer and Dr. Henn as President, Thomas J. DesRosier and Marella Thorell ceased serving as Co-Chief Executive Officers and Co-Presidents of the Company as of the Effective Date. Mr. DesRosier will continue to serve as the Company's Executive Vice President, Chief Legal Officer, and Ms. Thorell will continue to serve as the Company's Executive Vice President, Chief Financial Officer.

Exhibit 4.2

DESCRIPTION OF CAPITAL STOCK

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

Our authorized capital stock consists of:

- 360,000,000 shares of common stock, par value $0.001 per share; and
- 10,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

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

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

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

Dividend

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

Preferred Stock

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Exhibit 10.19

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this "Agreement"), dated as of the date of last signature below (the "Effective Date"), is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and Kelly Brady ("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 August 16, 2023 by and between the Company and Executive (the "Prior Agreement").

B. Executive and the Company mutually desire that Executive continue to be employed by 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, 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 Senior Vice President, Clinical Development of the Company, initially reporting directly to the Chief Executive Officer ("Supervisor" or "CEO") of the Company, with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to Executive by the Supervisor or such other Company officer may determine. 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 $414,300 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 Company (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 of Directors of the Company or an authorized committee of the Board (in either case, the "Board"). Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 35% 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 and may be pro-rated for any partial year of employment. 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.

(g) Equity. Subject to approval by the Board, the Company will grant Executive, under the Company's 2015 Incentive Award Plan (the "Plan"), an award of 75,000 restricted stock units (the "RSUs") under the Plan (subject to adjustment for corporate events as set forth in the Plan), which will vest 100% on September 30, 2025, subject to Executive's continued service to the Company. In all respects, the RSUs will be governed by and subject to the terms of the Plan and a separate RSU award agreement to be entered into between Executive and the Company. Further, for sake of clarity, any stock options and RSUs issued to Executive during their employment with Company, prior to signing this Agreement, will continue to vest in accordance with the existing option and RSU agreements executed by Executive and Company.

(h) Retention Bonus. Executive will be paid a one-time retention bonus of $200,000 (the "Retention Bonus"), which shall be paid in two equal installments of $100,000 each on June 30, 2025 and December 30, 2025, subject to Executive's continued service to the Company.

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) 0.75 times (y) the Annual Base Salary, payable in the form of salary continuation in regular installments over the 9-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"), 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) 0.75 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.

(iv) any remaining Retention Bonus installments due to Executive if a Termination without Cause or Change in Control occurs prior to the last Retention Bonus installment on December 30, 2025.

(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, which shall not include a determination by the Company's CEO or the Supervisor that Executive will report to another Company officer as contemplated by Section 1(c), (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 Legal 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. 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 considered nonqualified deferred compensation under Section 409A and 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. <u>Executive Acknowledgement</u>.

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:_____
Name: Thomas J. DesRosier
Title: EVP, Chief Legal Officer

_____
Kelly Brady

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Kelly Brady ("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 Employment Agreement, dated as of [_____, 2025] (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; 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 corporate 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 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 7 business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the Chief Legal Officer 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. Protected Disclosures. 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 (i) communicating directly with, cooperating with, or providing information to, or receiving financial awards from, any federal, state or local government agency, including without limitation the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, the U.S. Department of Justice, the U.S. Equal Employment Opportunity Commission, or the U.S. National Labor Relations Board, without notifying or seeking permission from the Company or (ii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Employee has reason to believe is unlawful.

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.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated:

Kelly Brady

SERES THERAPEUTICS, INC.

Dated:

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-3 (Nos. 333-273794 and 333-282450) and Form S-8 (Nos. 333-205253, 333-210171, 333-223514, 333-230092, 333-236824, 333-253776, 333-263134, 333-269081, 333-270319, 333-277658, 333-285769 and 333-287027) of Seres Therapeutics, Inc. of our report dated March 12, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 12, 2026

Exhibit 31.1

CERTIFICATIONS

I, Richard N. Kender, 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 12, 2026

By: /s/ Richard N. Kender
Richard N. Kender
Executive Chair and Interim Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Marell Thorell, 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 12, 2026

By: /s/ Marella Thorell
Marella Thorell
Executive Vice President, Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard N. Kender, Executive Chair and Interim 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, 2025 (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 12, 2026

/s/ Richard N. Kender
Richard N. Kender
Executive Chair and Interim Chief Executive Officer (*Principal Executive Officer*)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Marella Thorell, Executive Vice President, Chief Financial 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, 2025 (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 12, 2026

/s/ Marella Thorell
Marella Thorell
Executive Vice President, Chief Financial Officer
(*Principal Financial and Accounting Officer*)