
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

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 1-38519

Serina Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

82-1436829

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

601 Genome Way, Suite 2001

Huntsville, Alabama 35806

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(256) 327-9630**

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, par value \$0.0001 per share	SER	NYSE American

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 "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

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 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 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 Exchange Act): Yes No

The aggregate market value of the voting common stock held by non-affiliates of the registrant, computed based on the closing price for such stock as reported on the NYSE American on June 30, 2025 (the last trading day of the registrant's second fiscal quarter of 2025) was \$21.8 million.

As of March 18, 2026, there were outstanding 12,314,159 shares of common stock, par value \$0.0001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed for the registrant's 2026 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

[Table of Contents](#)

Serina Therapeutics, Inc.
Table of Contents

	Page Number
Part I	
Item 1. Business	5
Item 1A. Risk Factors	29
Item 1B. Unresolved Staff Comments	74
Item 1C. Cybersecurity	74
Item 2. Properties	75
Item 3. Legal Proceedings	75
Item 4. Mine Safety Disclosures	75
Part II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	76
Item 6. Reserved	76
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	76
Item 7A. Quantitative and Qualitative Disclosures about Market Risk	87
Item 8. Financial Statements and Supplementary Data	88
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	119
Item 9A. Controls and Procedures	119
Item 9B. Other Information	120
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	120
Part III	
Item 10. Directors, Executive Officers, and Corporate Governance	1
Item 11. Executive Compensation	1
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	1
Item 13. Certain Relationships and Related Transactions, and Director Independence	1
Item 14. Principal Accountant Fees and Services	1
Part IV	
Item 15. Exhibits and Financial Statement Schedules	122
Item 16. Form 10-K Summary	124
Signatures	125

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Report" or this "Annual Report") contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology.

Any forward-looking statements in this Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other 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 these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those discussed in this Report under Part 1, Item 1A in this Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

The description or discussion, in this Report, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.

Summary of Risk Factors

Our business is subject to a number of risks that, if realized, could materially affect our business, prospects, operating results and financial condition. These risks are discussed more fully in the “Risk Factors” section of this Annual Report. These risks include, but are not limited to, the following:

- We have a history of operating losses that are expected to continue for the foreseeable future, and we are unable to predict the extent of future losses, or whether we will generate significant revenues or achieve or sustain profitability.
- We need additional financing to execute our operating plan and continue to operate as a going concern.
- Our product candidates are at an early stage of development and may not be successfully developed or commercialized.
- Preliminary results from our nonclinical studies and clinical trials that we announce or publish from time to time may change as more patient data becomes available and as the data undergoes audit and verification procedures.
- The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans, and we may fail to obtain regulatory approval of our product candidates.
- Failure of our technology would significantly harm our business, results of operations, and prospects.
- We may seek designations under FDA programs designed to facilitate and potentially expedite product candidate development, such as fast track or breakthrough therapy designation. Our product candidates may not receive any such designations or if they do receive such designations they may not lead to faster development or regulatory review or approval and it does not increase the likelihood that our product candidates will receive marketing approval.
- If we are unable to obtain approval via the accelerated approval pathway, we may be required to conduct additional nonclinical studies or clinical trials. Even if we receive accelerated approval from the FDA, the FDA may seek to withdraw accelerated approval.
- If we apply for orphan drug designation from the FDA, there is no guarantee that we will be able to obtain or maintain this designation, receive this designation for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent our regulatory approval or commercialization or limit our commercial potential.
- We may form or seek strategic partnerships or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.
- We rely on contract manufacturing organizations to manufacture our nonclinical and clinical pharmaceutical supplies and expect to continue to rely on CMOs to produce commercial supplies of any approved product candidate, and our dependence on CMOs could adversely impact our business.
- We rely on third parties to conduct some of our nonclinical studies and all of our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for, or commercialize, our product candidates when expected or at all.
- We rely on other third parties to store and distribute our product candidates for nonclinical studies and clinical trials that we conduct.
- We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates. If any product candidate that we successfully develop does not achieve broad market acceptance

[Table of Contents](#)

among physicians, patients, health care payors and the medical community, the revenues that we generate from their sales will be limited.

- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.
- We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.
- Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, reimbursement practices, or health care reform initiatives, which would harm our business.
- Our success is largely based upon our ability or partner's ability to scale our intellectual property and proprietary technologies, and we may be unable to protect and/or enforce our intellectual property.
- We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.
- If we or our partners are sued for infringing on the intellectual property rights of third parties, it could be costly and time consuming, and an unfavorable outcome in any such litigation could have a material adverse effect on our business.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- If we do not obtain patent term extension for our drug candidates, our business may be materially harmed.
- Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our technologies and product candidates.
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.
- The FDA regulatory approval process is lengthy, time consuming, and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.
- Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.
- Our future success depends on our ability to recruit and retain our executive team and key scientists and to attract, retain, and motivate qualified personnel.
- We expect to expand our development, regulatory, and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.
- If we do not continue to satisfy the NYSE American continued listing requirements, our Common Stock could be delisted from NYSE American.
- Anti-takeover provisions in our governance documents and under Delaware law could make an acquisition of Serina more difficult and may prevent attempts by our stockholders to replace or remove our management.
- We do not anticipate paying any cash dividends in the foreseeable future.
- Conflicts of interest may arise from our relationship with Juvenescence, which will own a significant percentage of our common stock as well as warrants to purchase additional shares of our common stock and will be able to substantially influence the Company and exert control over matters subject to stockholder approval.

PART I

Item 1. Business

Overview

We are a clinical-stage biotechnology company developing a pipeline of wholly-owned drug product candidates to treat neurological diseases and other indications. Our POZ drug delivery technology is designed to enable certain existing drugs and novel drug candidates to be modified in a way that provides the potential to improve the integrated efficacy and safety profile of multiple modalities including small molecules, RNA-based therapeutics and antibody-based drug conjugates (ADCs). The Company's proprietary POZ technology is based on a synthetic, water soluble, low viscosity polymer called poly(2-oxazoline) and is engineered to provide greater control in drug loading and more precision in the rate of release of attached drugs delivered via easy-to-administer, long-acting subcutaneous injection.

The therapeutic agents in our small molecule product candidates are typically well-understood and marketed drugs that are effective but are limited by pharmacokinetic ("PK") profiles that can include toxicity, side effects and short half-life. We believe that by using POZ technology, drugs with narrow therapeutic windows can be designed to maintain more desirable and stable levels in the blood. We believe that POZ technology can be applied to small molecules, proteins, ADCs, and other classes of molecules.

The chemical attachment of water-soluble polymers, in particular polyethylene glycol ("PEG"), to drugs has become a valuable technique for improving the properties of pharmaceuticals. This technique has been successfully employed in producing many FDA-approved drugs. We believe that there is an unmet need for polymer delivery technology that addresses the limitations of PEG and other biocompatible polymers and that the POZ technology has the following advantages:

- Synthesis and stability – POZ is produced using inexpensive starting materials in essentially a "one pot" synthesis and is stable at room temperature. PEG is comprised of repeating units of ethylene glycol. PEG is synthesized by ring opening polymerization of ethylene oxide. Ethylene oxide is a flammable, toxic, explosive and colorless gas. High quality PEG is available from only a few industrial-scale facilities, and is relatively expensive. The manufacturing process is quite dangerous and is typically not done in research laboratories and not in FDA-approved GMP manufacturing facilities. The final PEG product is susceptible to air oxidation and must be stored with great care, in the dark and under inert atmosphere. In contrast, POZ is synthesized by ring opening polymerization of 2-ethyl 2-oxazoline or 2-methyl 2-oxazoline. These monomers are clear liquids, stable at ambient conditions, not explosive or toxic, are available from many sources at relatively low cost, readily purified and easily handled in the average chemical laboratory. Moreover, drug-POZ conjugates are not susceptible to air oxidation and can be stored at room temperature or in a refrigerator. We have not performed comparisons of PEG-conjugated molecules versus POZ-conjugated molecules in humans. However, we have made these comparisons in certain PEG-conjugated molecules versus POZ-conjugated molecules in vitro and in animal studies.
- Non-immunogenic or reduced immunogenicity – In studies to date, POZ has not elicited an immune response or stimulated significant development of antibodies to POZ. We conducted preclinical studies where repeat dosing of POZ polymer in rabbits did not generate anti-POZ antibodies. The clinical trial of our proof-of-principle molecule, SER-214, a first example of POZ in humans, also showed no toxicity concerns.
- Drug loading and release – POZ enables greater drug loading than PEG, with highly programmable drug release kinetics to enable continuous drug delivery. Drug loading with PEG is low and can occur only at the end of the polymer chains (n=1 or 2 copies of drug). Drug loading with POZ is high and is accomplished by attaching multiple drug copies (n= 10 or higher) to the side chain of the polymer backbone. The number of POZ attachment points can be controlled and appears to be unlimited. Higher drug loading per mole of polymer means that less amount of POZ polymer is required when compared to PEG polymer for delivery of the same amount of active drug.

Table of Contents

- No accumulation –Studies to date indicate that POZ does not accumulate in tissues when given at dose levels anticipated to be given to humans, is not metabolized, and is cleared almost entirely through renal filtration. Preclinical IND-enabling studies in rodents and monkeys indicate that POZ is cleared from the body by renal filtration and as an intact polymer with no evidence of accumulation in any tissue. In contrast PEG is known to accumulate in several tissues including the liver, spleen, muscle, brain and kidney.
- Targeting – POZ offers multiple substitution sites, which allows for simultaneous attachment of several copies of a drug along with a targeting molecule. Multiple copies of drugs can be attached to a single POZ polymer backbone. The end of the POZ polymer chain has a different, orthogonal functional group from those along the backbone, and this property has been used to attach a targeting moiety such as an antibody or peptide.

Our business is largely focused on the development of a wholly-owned pipeline of POZ-enabled drug candidates for CNS indications, including Parkinson’s disease. Our lead product candidate, SER 252 (POZ-apomorphine), is a POZ conjugate of the potent dopamine agonist apomorphine being developed for the treatment of Parkinson’s disease and is in clinical development. SER 252 is designed to provide CDS via a subcutaneous injection delivered one to two times per week. CDS is a long-sought clinical strategy for Parkinson’s disease that currently approved therapies fall short of delivering.

We intend to develop other potential applications of the POZ technology, such as therapeutics delivered through Antibody Drug Conjugates ("ADCs") and Lipid Nanoparticle ("LNP") technology, through partnerships. Our SER 214, a POZ conjugate of rotigotine for the treatment of early Parkinson’s and Restless Leg Syndrome, was our first product candidate advanced into human study and has completed a Phase Ia study in 19 subjects. This product candidate served as a proof of principle for our POZ technology. This candidate is not being advanced internally. We intend to potentially out-license this product candidate.

Our Development Pipeline

We believe that our POZ platform delivery technology has potential for use across a broad range of payloads and indications. Among our development candidates, we intend to internally advance SER 252 for advanced Parkinson’s disease. We do not believe we will require a license to the API associated with SER 252. We are advancing our research and development efforts for POZ technology in LNP delivered ribonucleic acid (“RNA”) vaccines for infectious diseases. We intend to advance additional applications of the POZ platform via out-licensing, co-development, or other partnership arrangements. These applications may include other CNS disorders and POZ LNP relevant disease fields. In January 2026, we received FDA clearance of IND application for our lead product candidate, SER-252 for the treatment of advanced Parkinson's disease. In February 2026, we enrolled and dosed our first patient in our Phase 1b clinical trial for SER-252.

Small Molecule Pipeline

Drug Candidate	Indication	Preclinical	IND enabling	Phase 1	Phase 2	Phase 3
SER-252 POZ-apomorphine	Advanced Parkinson’s					
SER-270 POZ-VMAT2i	Tardive Dyskinesia					
SER-290 POZ-undisclosed	Undisclosed CNS					

Platform Partnering Programs

Drug Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
POZ-RNA	Immunotherapy				
POZ-ADC / AOC	Oncology				

Our Strategy

Our strategy is to develop and commercialize polymer therapeutics based on conjugation of suitable small molecules to our proprietary POZ. While prior polymer technologies such as PEG focused primarily on protein conjugation, we envisioned the need to develop a polymer therapeutics platform that could address the vast universe of small molecules and program their release. We have demonstrated in multiple preclinical animal studies that POZ can program the release of small molecules, particularly those that have solubility challenges and PK limitations. We believe that specific POZ conjugated small molecules can be delivered continuously following a single injection. As a “platform technology,” we anticipate this technology has the potential for development of drug candidates across a broad range of payloads and indications. We intend to focus on our current pipeline of candidates and selectively explore new molecules for potential internal development. In parallel, we intend to expand our collaboration activity with prospective partners that have compounds that could potentially benefit from our POZ polymer platform technology. To achieve this, we intend to:

- Advance our lead program, SER 252, which addresses a large unmet need for CDS for late stage Parkinson’s patients;
- Seek to create economic and strategic value through POZ LNP licensing and partnerships across multiple RNA-based therapeutic indications;
- Seek to create economic and strategic value for other applications of the POZ platform, including ADCs;
- Continue to expand upon applications of the POZ platform with a view to capitalize on the potential of the technology to enable additional payloads and product opportunities; and
- Continue to expand a network of academic and biopharmaceutical collaborations and commercial partnerships to develop and potentially validate other applications of the POZ platform.

POZ Development Background

Over the past 25 years, chemical attachment of water-soluble polymers, in particular, polyethylene glycol, to drugs has become a valuable technique for improving the properties of pharmaceuticals. This technique has been successfully employed in producing second-generation forms of several FDA-approved drugs.

A polymer drug delivery approach involves using polymers, which are large molecules composed of repeating subunits, to design drug delivery systems that can control the release of medications in a controlled and targeted manner. Polymer-based drug delivery systems can enhance the therapeutic outcomes of drugs by optimizing their PKs, improving patient compliance, and reducing side effects. Some key aspects of polymer drug delivery are as follows:

- **Controlled Release:** Polymers can be engineered to release drugs at a controlled and predetermined rate. This enables sustained drug levels in the body, reducing the need for frequent dosing and maintaining therapeutic concentrations over an extended period.
- **Targeted Delivery:** Polymer drug delivery systems can be designed to target specific tissues, cells, or organs with a high concentration of the drug while minimizing systemic exposure. This precision targeting reduces the exposure of healthy tissues to the drug, minimizes side effects, and increases the drug’s effectiveness.
- **Improved Bioavailability:** Some drugs have low solubility or stability in the body, limiting their absorption and therapeutic efficacy. Polymers can be used to improve the solubility and stability of such drugs, allowing for better bioavailability.
- **Protection of Labile Drugs:** Polymers can protect labile or sensitive drugs from degradation in the harsh conditions of the gastrointestinal tract, allowing for oral delivery of drugs that would otherwise be ineffective when taken orally.
- **Reduced Toxicity:** Polymer encapsulation can help reduce the toxicity of certain drugs by controlling their release and preventing peak concentrations that can lead to adverse effects.

[Table of Contents](#)

- Long-Acting Formulations: Polymer-based formulations can extend the duration of drug action, reducing the frequency of administration. This is particularly useful for chronic conditions where adherence to treatment is crucial.
- Biodegradable Polymers: Some polymer drug delivery systems are made from biodegradable materials that gradually break down in the body, eliminating the need for removal or extraction of delivery devices.

Common polymer-based drug delivery systems include:

- Microspheres and nanoparticles: Tiny particles made from biocompatible polymers that encapsulate and release drugs.
- Hydrogels: Cross-linked polymer networks that can hold a large amount of water and release drugs in response to environmental cues.
- Implants: Solid polymer devices that can be surgically implanted for long-term drug delivery.
- Liposomes: Lipid-based vesicles that can encapsulate drugs and deliver them to specific sites.

Polymer drug delivery approaches offer versatility and customization, allowing for the design of drug delivery systems tailored to the specific needs of a drug and our intended therapeutic application. These approaches have the potential to enhance the safety and efficacy of medications while improving patient compliance and convenience.

Serina was formed with the goal of inventing a polymer that was distinct from PEG that could be used for modification of drugs. Our research over the past fifteen years has led to the development of a new polymer technology based on poly(2-ethyl-2-oxazoline). Our POZ technology is designed to be a “platform technology” in that we anticipate that multiple products can be developed using the same basic polymer. Serina was first to develop and patent methods to produce polymers of POZ suitable for pharmaceutical applications.

Our Product Candidates

Serina intends to focus on advancing our SER 252 POZ-apomorphine drug candidate and selectively explore new molecules for potential internal development, co-development and partnering. Current candidates include:

SER 214 (POZ-rotigotine) was the first product from our pipeline to be advanced into humans. Serina initiated a Phase Ia trial in July 2015 in 19 stably treated Parkinson’s subjects. The trial was completed in January 2017 with data published in a June 2020 article in *Movement Disorders*. This was a single and multi-dose, dose-escalation study in patients who were not experiencing significant motor fluctuations. Patients in the study were allowed to be on existing therapy for Parkinson’s disease, or be on no therapy, but have a definitive diagnosis of Parkinson’s disease. We have not internally advanced SER 214 beyond Phase Ia and will seek to partner on any further development. We believe the SER 214 program, while not being advanced internally, provided data important to the development of a POZ dopamine agonist (such as rotigotine and apomorphine) conjugate to enable CDS in Parkinson’s patients. This research led to the development of SER 252.

SER 252 (POZ-apomorphine). We have advanced SER 252 into Phase I clinical trials in February 2026 for patients with advanced Parkinson’s disease. The treatment of advanced Parkinson’s disease relies on multiple therapies, including levodopa (“L-DOPA”), compounds that inhibit the breakdown of L-DOPA in the brain (catechol-O-methyl transferase, or COMT; for example, opicapone), dopamine agonists (transdermal rotigotine; for example, Neupro™) and others. L-DOPA in escalating doses is the mainstay of therapy for advanced Parkinson’s disease but is also the proximate cause of LIDs, one of the most troubling complications of prolonged high dose L-DOPA therapy. Approximately 90% of Parkinson’s disease patients who use L-DOPA for ten years will develop irreversible LIDS. An infusion therapy known as Onapgo (apomorphine) is now available in the United States after its approval by the FDA on Feb. 4, 2025. Onapgo must be administered as a 12–16-hour continuous infusion through an electronic pump and a standard insulin infusion set. While effective in reducing daily “OFF” time, and simultaneously increasing daily “ON” time without troublesome dyskinesia, usage frequently requires a healthcare provider to hook up the device and infusion each day and remove it at night. “OFF” time refers to the time period the patient is unable to perform routine daily activities. “ON” time refers to those periods where the patient is able to perform routine daily activities. Onapgo is confounded by significant skin reactions in approximately 40% of patients, often leading to permanent scarring (nodules) on the abdomen. Our preclinical studies in

[Table of Contents](#)

monkeys suggest SER 252 may be administered as a single subcutaneous injection twice a week, provides continuous delivery of apomorphine and has no skin liabilities. Our use is designed to be administered in the convenience of the patient's home without the need for a healthcare provider. We believe that SER 252 may allow some patients to titrate completely off L-DOPA, thus simultaneously addressing the LIDS that is associated with our prolonged use.

POZ-lipids. We are advancing preclinical research focused on POZ-lipids as a non-immunogenic (or markedly reduced immunogenic) alternative to the PEG-lipids in the lipid nanoparticles (LNP) currently approved for the COVID-19 vaccines developed by Pfizer/BioNTech and Moderna. Both of the currently approved vaccines contain 1-2 mol% PEG-lipid, which is required to stabilize the LNP and prevent fusion of nascent particles. We have prepared LNPs from POZ-lipids and demonstrated these can stably incorporate oligonucleotides and transfect cell lines. We believe that it is likely that the global population is being progressively immunized against PEG due to the presence of PEG-lipids in the currently approved vaccines, combined with upwards of 70% of the population already having some level of anti-PEG antibodies. PEG is used at low molecular weights in a wide range of consumer products including cosmetics, toothpaste, deodorants, and laxatives. Anti-PEG antibodies are implicated in some of the serious adverse reactions such as anaphylactic reactions seen following the COVID-19 vaccine administration. Most infectious disease experts believe that COVID-19 will become an endemic challenge and that booster immunizations will be required. We believe that the anti-PEG antibody issue potentially has the unintended consequence of compromising the efficacy of the next generation of vaccines due to accelerated blood clearance. We previously entered into preclinical feasibility studies with two major pharmaceutical companies toward the goal of developing "PEG-alternative" LNP vaccines for infectious diseases. The LNP delivered RNA therapeutics field represents one of the most promising areas of drug development, with over 1,200 LNP delivered RNA-based therapeutics in development. Our intent is to license the POZ technology to companies developing LNP approaches in infectious diseases, cancer immunology, and gene therapy.

Parkinson's Disease

Parkinson's disease is a chronic, disabling disorder that results from a deficiency of dopamine in the brain. Dopamine deficiency results from a degeneration of dopaminergic neurons in a portion of the brain known as the substantia nigra. Treatment for Parkinson's disease has focused on mechanisms for delivery of dopamine precursors (levodopa, which can be delivered by daily pills or intestinal infusion), or on mechanisms that delay or prevent the breakdown of dopamine in the brain. The majority of patients who are diagnosed with Parkinson's disease are treated with oral formulations of levodopa that include carbidopa, a compound that inhibits the breakdown of levodopa. Other approaches include selective inhibitors of monoamine oxidase enzymes in the brain ("MAO-B"), or dopamine agonists, such as rotigotine (the active ingredient in the transdermal patch Neupro™), ropinirole or pramipexole. In almost all instances of oral treatment with any of these compounds, patients may experience "wearing off" where the drug fails to deliver an adequate dopaminergic stimulus after being used for months to years or the drugs may promote a disabling side effect known as dyskinesia (involuntary movements of the extremities). We believe that there is a major need for new therapies that can treat patients with Parkinson's disease, extend their productive years, and ameliorate these unwanted side effects.

In recent years, the clinical strategy of CDS has been advanced in both animal and human studies. Most oral drugs deliver dopaminergic stimulation in a phasic peak and trough fashion. Animal studies show that such phasic alterations in dopaminergic tone may result in accelerated degeneration of dopaminergic neurons in the brain, and lead to motor complications known as dyskinesia. Preclinical animal studies also suggest that continuous delivery of apomorphine appears to delay the degeneration of dopaminergic neurons in the brains of affected animals, thus delaying some of the side effects of dopaminergic therapy as well as the onset of late-stage Parkinsonism. In a double-blind, double-dummy study in humans employing an intestinal infusion of levodopa-carbidopa gel ("LCIG") in advanced Parkinson's patients, continuous intestinal infusion of levodopa gel was shown to be superior in outcomes to oral, sustained release levodopa-carbidopa capsules. The results showed that an intestinal infusion of levodopa-carbidopa gel in the proximal small intestine (delivered by a percutaneous catheter) increased patients' "ON" time without troublesome dyskinesia by approximately two hours per day, and decreased "OFF" time by the same amount. The approach was the first CDS product approved by the FDA (AbbVie's Duopa). Notwithstanding the significant increase in patient clinical outcomes in advanced Parkinson's patients, the approach is invasive, requires surgery to place a percutaneous catheter (with risk of infection, perforation of the intestine or inadvertent removal), frequent loading of levodopa-carbidopa gel packs, and frequent flushing to keep the catheter flowing. Subsequently, another product providing CDS (AbbVie - Vyalev) was approved by the FDA (October 2024). The Vyalev product is a liquid formulation of the prodrugs foslevodopa-foscarbidopa that is continuously infused subcutaneously using an electronic pump. This represented a substantial new treatment option for advanced Parkinson's disease patients.

Our POZ technology platform has attributes that we believe has the potential to allow POZ-conjugates to deliver on the approach of prolonging the PKs of attached drugs, thus enabling continuous drug delivery.

SER 214 – Provides Continuous Release of Rotigotine Following a Single Weekly Subcutaneous Injection in Parkinson’s Disease Patients with Early Stable Disease

The potent dopamine agonist rotigotine is attached to pendent POZ with programmable linkers that allow the rotigotine to be released slowly, following a single subcutaneous injection of SER 214 in a standard insulin syringe. Preclinical animal studies in rats and monkeys have shown that SER 214 appears to provide a continuous state of dopaminergic tone for approximately one week following a single subcutaneous injection. Repeat-dose preclinical studies in rats (12 weeks), dogs (single dose maximum tolerated dose study) and monkeys (results of a 4-week study, plus the 90-day study in cynomolgus macaques that was part of the IND toxicology program) show the week-to-week variation in plasma release of rotigotine (plasma half-life) and drug exposure do not change dramatically following a single subcutaneous injection each week. Based on these IND enabling studies, SER-214 was advanced into a Phase Ia study in humans.

SER-214 was our first product candidate to be advanced into humans, completing a Phase Ia study in 19 patients. While SER-214 has not been advanced beyond this Phase Ia trial, the program provided clinical data important to the development of our POZ platform’s capability to enable CDS of a dopamine agonist for treatment of Parkinson’s patients. This research led directly to the development of our follow on IND candidate, SER 252. The Phase Ia study demonstrated SER 214 was well-tolerated when delivered in a standard insulin syringe. The data for the final two weeks of Cohort 3 (high dose cohort) are shown in Figure 3. Subjects received an initial dose in week one of 50 mg SER 214, followed by a single dose of 100 mg SER 214 in week two, and then followed by a single 200 mg dose of SER 214 in weeks three and four. This dosing was followed by a one-week wash-out period. The SER 214 Phase Ia study was not designed with a placebo arm, and therefore statistical analysis of the observed data does not have p-values. SER 214 demonstrated predictable PK that paralleled the PK results observed in preclinical studies in monkeys. The results of the PK for released drug (rotigotine) are shown below, along with the published data for the 3 mg transdermal rotigotine patch.

Figure 1: Pharmacokinetic profile of SER 214 in Parkinson’s disease subjects in Phase Ia

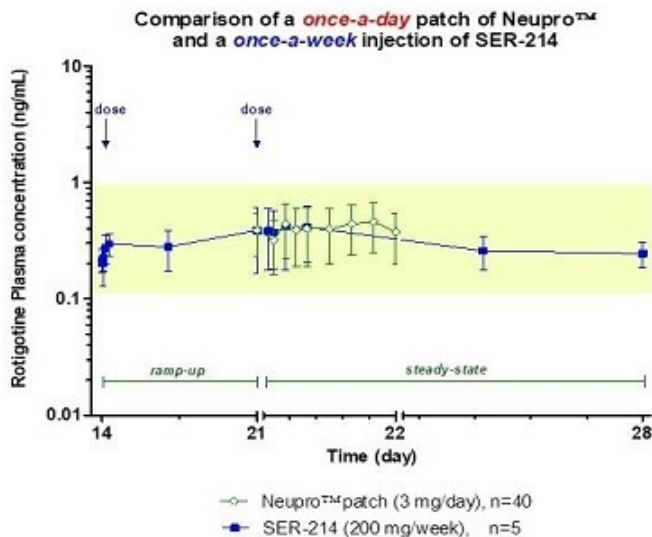


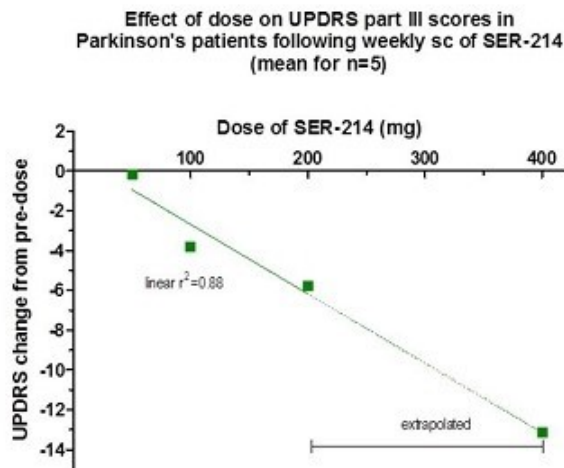
Figure 1: PK profile of released drug in Parkinson’s disease subjects who received an initial dose of 50 mg SER 214, followed by a single dose of 100 mg SER 214, and then two weekly doses of 200 mg SER 214. Levels of released drug (rotigotine) are indicated in ng/ml. The yellow shaded area is the therapeutic window for rotigotine. Also shown in green is a 24-hour period for plasma levels of rotigotine from the 3 mg Neupro patch (UCB, published data). From the data, it would appear a weekly injection of SER 214 of 200 mg (in 1 mL) approximates the levels of rotigotine from the daily 3 mg transdermal patch.

[Table of Contents](#)

The results in Figure 1 show that a single weekly injection of SER 214 provided continuous drug delivery in the predicted therapeutic window where plasma levels of rotigotine would be expected to provide control of symptoms of early Parkinson's (yellow shaded area). The 200 mg dose of SER 214 provided plasma levels of rotigotine that are approximately the same as the 3 mg Neupro™ patch but did so for an entire week. In data not shown, plasma levels of released rotigotine fell below detectable levels approximately nine days after the final injection, indicating that released rotigotine is released at a near steady-state level for an entire week following a single weekly subcutaneous injection.

The Phase Ia study also measured the potential for efficacy, which relies on a change from baseline in the Unified Parkinson's Disease Rating Score ("UPDRS"). One component of the UPDRS measures the change in motor scores; this is known as UPDRS (Part III) and is measured by the physician who evaluates if there is a change in scores when the patient returns to the clinic for follow-up. A change from baseline of negative scores indicates improvement and the FDA has used UPDRS (Part III) as part of an approvable endpoint. In Cohort 3, subjects had a mean change from baseline of approximately -6 at day 28 – indicating that SER 214 may be improving their signs and/or symptoms of Parkinson's disease. There appeared to be a dose-dependent change from baseline as the doses were increased. This is shown in Figure 3 below.

Figure 2: Effect of dose of SER 214 on change from baseline in UPDRS (Part III)



Subjects who completed the final two weeks of dosing were shown to be at steady-state release. The plot above shows the relationship between dose and change from baseline in UPDRS (Part III). At the highest dose evaluated (200 mg) there was an approximate -6 point change in UPDRS. When extrapolated to a 400 mg dose, which would approximate the 6 mg Neupro™ patch in terms of released rotigotine, there would be an estimated -13 point change in UPDRS (Part III). We believe such a degree of change would achieve an approvable endpoint. The extrapolated data was not an actual result of the study and there can be no assurance that this result is able to be achieved. The method of extrapolation is industry standard based on a near linear relationship (shown in figure as linear $r^2 = 0.88$) with the data from the actual study.

The relationship between dose and steady-state PK levels of released rotigotine revealed a linear relationship as shown in Figure 3. Extrapolation of the dose of SER 214 to higher doses of 400-600 mg is predicted to result in steady-state levels of rotigotine equivalent to the 6 mg and 8 mg Neupro™ patch. Such higher doses would require a device to deliver the higher volumes (2-3 mL).

Figure 3:

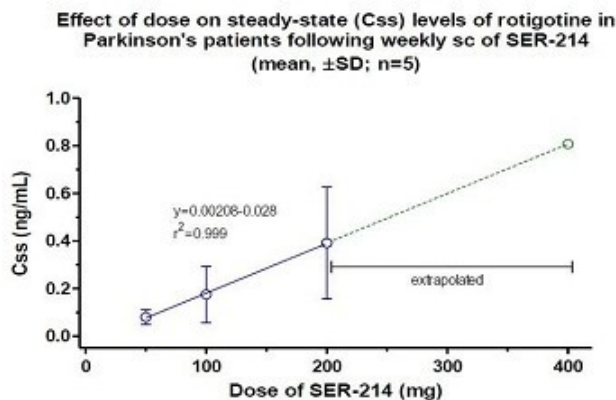


Figure 3: Relationship between dose of SER 214 administered in the last two weeks of dosing in the 50 mg, 100 mg, and 200 mg cohorts and mean (\pm SD) steady-state levels of released rotigotine.

The primary safety endpoint for the SER 214 Phase Ia study was adverse events. There were no deaths or serious adverse events during the study. One subject in cohort 2 discontinued because of the development of generalized hives shortly after the 50-mg injection of SER 214. These rapidly cleared with administration of a single antihistamine dose and were not associated with any additional systemic complaints. All adverse events were mild to moderate in intensity, and all recovered by the end of the study. There was no apparent dose relationship, and no patient experienced new onset or worsening of dyskinesia.

[Table of Contents](#)

In summary, the Phase Ia study demonstrated SER 214 is a well-tolerated injection when administered subcutaneously in stable patients with early signs of Parkinson's disease. Steady-state levels of released rotigotine were linear with dose, and physician assessment of UPDRS (Part III) suggested evidence of a dose-dependent decline from baseline - even in these stably treated patients. We believe that SER 214 is a promising product candidate that may be used to treat patients with early Parkinson's disease, and market research suggests patients and physicians would readily use this approach at home without the need for an office visit or home health care professional. In June 2020, the results of the Phase Ia trial were published in *Movement Disorders*. We have not internally advanced SER 214 beyond Phase Ia and will seek to partner on any further development.

SER 252 (POZ-apomorphine) – Addressing the Need for a Potent Dopamine Agonist to Treat Advanced Parkinson's disease

We believe that the same polymer chemistry used in SER 214 to provide continuous delivery of rotigotine might be used to provide continuous release of other drugs that would be effective in advanced Parkinson's disease. One such drug is apomorphine, one of the most potent dopamine agonists known and the one most closely aligned chemically with the natural substance in the brain (dopamine). Apomorphine is approved as a "rescue" medication that is delivered as an injection (Supernus - Apokyn) analogous to an epinephrine injection for acute anaphylaxis. In Europe and some other parts of the world, there is an approved liquid formulation called Apo-go (Supernus) that has been used to manage the symptoms of advanced Parkinson's patients. Recently (February 2025), this product was approved by the FDA. In PD patients who develop severe "OFF" periods as a result of advancing disease associated with the "wearing off" of their medications, an Apokyn injection can promote "ON" periods within a few minutes. Many patients carry an Apokyn injection pen as a precaution for abrupt "OFF" periods. In contrast, Apo-go is administered via an electronic pump as a daily subcutaneous infusion 12-16 hours a day. In July 2018, the first randomized, placebo-controlled study of Apo-go versus placebo was published (known as the TOLEDO study). The results showed that daily subcutaneous delivery of apomorphine for 12-16 hours during the waking day resulted in a significant reduction of daily "OFF" time of approximately 2 hours.

While Apo-go resulted in a substantial improvement in "OFF" time, the subcutaneous route of administration is confounded by severe skin reactions. An example of these types of skin reactions is shown in Figure 4.

Figure 4: Skin reactions from subcutaneous Apo-go administration



Figure 4: A patient with advanced Parkinson's disease who uses daily subcutaneous infusions of Apo-go to reduce "OFF" time. Subcutaneous delivery of apomorphine resulted in ulceration of the skin with draining abscesses, and in rare instances, skin necrosis.

In the TOLEDO study, approximately 60% of subjects dose-adjusted their daily infusions of Apo-go downward based on skin reactions, and about 40% of patients experienced nodule formation. Nodules that result from subcutaneous apomorphine generally do not resolve.

While Apo-go represents a non-surgical approach to treatment of advanced disease in PD patients and provides the same degree of improvement in "OFF" time as the LCIG catheter and deep brain stimulation, many patients do not tolerate the daily subcutaneous infusions. The daily set-up often requires a healthcare provider to come in each day to help the patient

[Table of Contents](#)

administer the drug. We believe that development of a more convenient method of delivering apomorphine, without having to use a complicated infusion device or confounded by serious skin reactions, would be a major contribution to patient care.

SER 252 (POZ-apomorphine)

In early 2018, Serina initiated work on developing a polymer conjugate of apomorphine that could be delivered as a subcutaneous injection that is devoid of any skin reactions. The first step was attachment of apomorphine to the polymer. The chemistry of attachment and controlled release required attachment of ester-linked groups to both of the hydroxyl groups in apomorphine; one ester linkage attaches the apomorphine to the polymer backbone (linking group) and the other ester linkage caps the second hydroxyl (capping group). In the course of these studies, Serina discovered that the rate-limiting step in the release of apomorphine from the polymer was the release of the “capping linker.” After three and a half years of dedicated efforts to control the release kinetics of apomorphine, Serina identified SER 252 as the IND candidate. Importantly, SER 252 provides linear dose kinetics when administered in preclinical multi-dose studies in monkeys as shown in Figure 5 below.

Figure 5: Dose response of SER 252 in monkeys

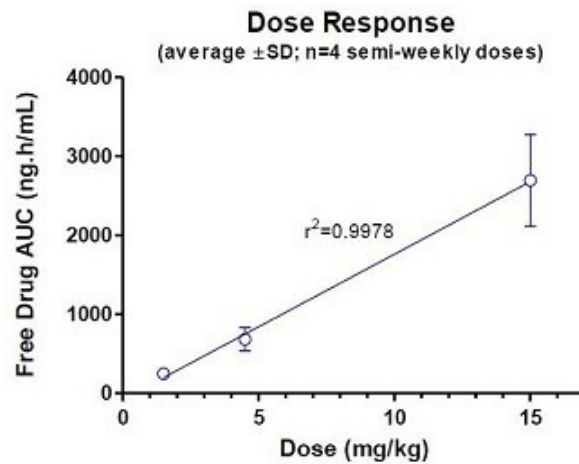


Figure 5: Young adult monkeys were dosed subcutaneous with SER 252 semi-weekly (n=4) at three different dose levels (1.5 mg equivalents Apo/kg, 4.5 mg equivalents Apo/kg and 15 mg equivalents Apo/kg) and daily levels of released apomorphine were determined. The AUC (area under the curve) for each set of doses was plotted versus dose administered.

PK Simulations for SER 252 in Patients with Advanced Disease

Although studies in humans are required for confirmation, Serina conducted a simulation of human PK based on the results from our preclinical studies in monkeys. The PK parameters of SER 252 in monkeys were modeled with a standard one-compartment fit of the data with V/F (volume of distribution) derived from imputed data from NeuroDerm, Ltd. published human PK on ND0701, an apomorphine product being developed by NeuroDerm; the V/F was 13 L/kg. The following results, which represent industry standard methodology for simulation, were obtained:

Figure 6:

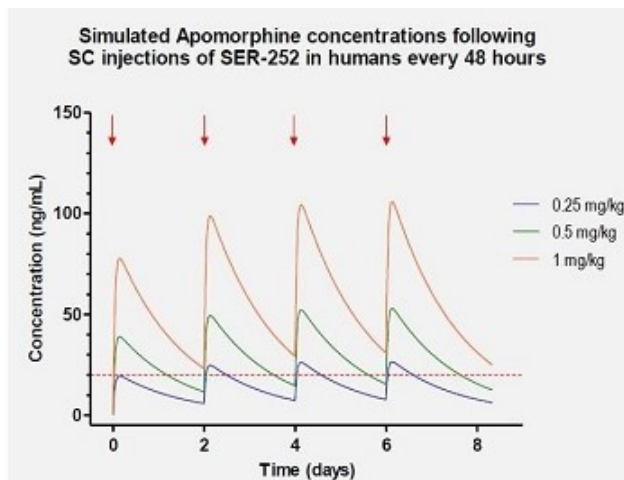


Figure 6: Simulations for human PK. The simulation demonstrated that doses from 0.25 mg eq Apo/kg to 1 mg eq Apo/kg would cover the PK profile of Apo-go and provide a range of doses that we intend to evaluate in early studies in humans.

There can be no assurance that the simulated result is able to be achieved. We believe these simulations suggest it may be possible to dose patients with advanced Parkinson’s disease with a subcutaneous injection that would provide levels of released apomorphine similar to the Apo-go infusion pump (a) without a trough level that would lead to an “OFF” period, (b) no need to have a healthcare provider hook up the device each day, and (c) no onerous skin reactions. We believe that the requisite trough level is likely in the range of about 3-5 ng/mL free apomorphine; plasma levels of apomorphine that “rescue” an acute “OFF” period about 4-5 ng/mL and persist for approximately 50 minutes (data from Cynapsus/Sunovion publications on development of a buccal apomorphine). The range of doses employed in an individual patient will likely vary, but the doses envisioned may potentially treat advanced disease and provide consistent “ON” time without troublesome dyskinesia and prevent the patient going into an “OFF” state. In multiple experiments in monkeys, SER 252 has not led to any skin reactions as a single or multi-dose regimen to date. We believe that it may be possible that this product candidate can be delivered in the patient’s home without the need for a healthcare provider.

If the results show SER 252 is well-tolerated with predictable PK, we expect to proceed to a Phase I MAD study in advanced patients in 2027. The results of the combined SAD/MAD studies will measure not only safety, PK and tolerability in these advanced patients but also daily “OFF” and “ON” time and will inform the design of the Phase II study. If Phase I is successful, we plan to have a meeting with the FDA to aid in design of a Phase II study.

Summary of Our Parkinson’s Disease Programs

SER 214 served as our proof-of-principle molecule to determine if our POZ conjugate technology could enable a long acting dopamine agonist in Parkinson’s disease. Our SER 252 product candidate leverages that research and development to potentially enable CDS in patients with advanced disease. A critically important observation was made in the TOLEDO study in that many patients down-titrated their oral L-DOPA doses by greater than 50% from their baseline dose. L-DOPA therapy is considered the mainstay of treatment of both early and advanced Parkinson’s disease, despite evidence that dopamine agonists are equally effective for early disease and do not promote the same degree of dyskinesia as levodopa. Approximately 50% of PD patients will develop LIDS within five years, and 90% within 10 years, of initiation of levodopa therapy. In one specialized center in Scotland, the Lees group has shown that fastidious titration of apomorphine (Apo-go) during the waking day can lead to complete off-titration of levodopa with a dramatic reduction in motor complications (45 of 64 patients achieved apomorphine monotherapy and titrated completely off oral levodopa). Patients who achieved monotherapy had an increase in “ON” time to 85% of the waking day. If SER 252 effectively prevents “OFF” time and delays or prevents dyskinesia in advanced disease, it might be possible to use SER 252 in patients with mid-stage disease to achieve significant control of symptoms without initiating levodopa therapy. At present, we are not aware of an effective alternative to oral levodopa. For patients who experience advancing disease that no longer responds to oral agonists, the default approach is to continue to escalate doses of levodopa with the consequence of accelerated onset of motor complications. We believe that there is significant potential for SER 252 to become such an alternative, potentially leading

[Table of Contents](#)

to a paradigm shift in how patients with Parkinson's disease might be treated. We believe that SER 214 and SER 252 may be administered in the home setting with the convenience and compliance of a single or twice-weekly subcutaneous injection that does not require a healthcare provider to administer, and patients may not need to continue therapy with levodopa (levodopa sparing strategy).

Licensing, Collaboration and Partnership Agreements

In early 2021, Serina entered into FSAs with several large pharmaceutical and biotechnology companies to advance POZ-lipids as a replacement strategy for PEG-lipids in the current mRNA vaccines. After two years of work with these partners, Serina entered into licensing discussions to advance POZ-lipids as a replacement for PEG-lipids.

In October 2023, Serina entered into a non-exclusive license agreement with Pfizer to use our POZ polymer technology for use in lipid nanoparticle drug delivery formulations. The agreement grants Pfizer non-exclusive rights to certain intellectual property, know-how, and proprietary technologies. Under the terms of the agreement, Pfizer is authorized to develop, manufacture, market, and commercialize products incorporating the licensed technology with respect to a specific POZ polymer structure in one field. The agreement outlines the protection and enforcement of intellectual property rights related to the licensed technology. Pfizer is obligated to use commercially reasonable diligent efforts to develop and commercialize licensed products, and to use such efforts to accomplish specified development and commercial objectives. The agreement includes a one-time upfront payment of \$3 million that was received on December 15, 2023, milestone payments payable to us upon the achievement of specific development, regulatory, and commercial milestones, and a royalty on net sales of products incorporating the licensed technology in accordance with the terms outlined in the license agreement. The range of royalties on sales of products is between 2.75% – 3.5% and is tiered to achievement of certain sales milestones.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We have sought patent protection in the United States and internationally related to the POZ technology. We own an extensive issued patent estate covering POZ technology and certain product candidates enabled by the POZ technology. We have applied for additional patents seeking to further protect and extend the POZ patent portfolio we own. Such applications may not result in issued patents and, even if patents do issue, such patents may not be in a form or scope that will provide us with meaningful protection for our product candidates. We also rely on trade secrets that are important to the development of our business. Trade secrets are difficult to protect and provide us with only limited protection, as trade secrets do not protect against independent development of technology by third parties.

We expect to file additional patent applications in support of current and new clinical candidates as well as in support of new applications of POZ platform technology. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending any such patents against third party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell, or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we file in the future, nor can we be sure that any patents that may be granted in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

Serina-Owned Intellectual Property

We have been issued a series of patents on various forms of POZ. The following is a list of patents that have been issued and published pending applications in the United States and worldwide. The list is presented by the individual family dockets. Expiration dates for non-domestic patent rights are based on a strict calculation of 20 years from the earliest filing date and, as such, Patent Term Adjustment in accordance with the jurisdiction could extend this term further than indicated.

[Table of Contents](#)

SER 01 Family: “Activated Polyoxazolines and Compositions Comprising the Same” (J. M. Harris *et al.*).

This family of patents provides methods of synthesis and compositions of terminally activated linear poly(oxazolines) having various terminal functional groups suitable for attaching to other molecules such as enzymes, proteins, lipids, and antibodies by stable linkages.

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
Japan	Utility	Granted	Feb-28-2008	2009-551999	Sep-19-2014	5,615,558	2-28-2028
Korea (South)	Utility	Granted	Feb-28-2008	10-2009-7020124	Mar-30-2015	10-1508617	2-28-2028
Korea (South)	Utility	Granted	Oct-25-2013	10-2013-7028233	Mar-30-2015	10-1508621	2-28-2028
US	Utility	Granted	Feb-28-2008	12/529,001	May-17-2011	7,943,141	2-28-2028
US	Utility	Granted	Mar-08-2017	15/453,686	Oct-02-2018	10,086,084	2-28-2028
US	Utility	Granted	Sep-27-2018	16/144,358	Dec-15-2020	10,864,276	2-28-2028

SER 02 Family: “Multi-armed Forms of Activated Polyoxazoline and Methods of Synthesis Thereof” (J. M. Harris *et al.*).

This patent provides branched poly(oxazolines) having a terminal activating group that can be linked to a second moiety such as a drug molecule. The branched or multi-arm composition generally comprises two or more linear poly(oxazolines) linked to a single branching point.

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
US	Utility	Granted	Sep-29-2008	16/680,448	Jan-03-2012	8,088,884	9-29-2028

SER 03/07 Family: “Multifunctional Forms of Polyoxazoline Copolymers and Drug Compositions Comprising the Same” (K. Yoon *et al.*).

This family of patents provides for poly(oxazolines) having a set of pendent functional groups on the polymer backbone and a terminal functional group, wherein the pendent functional groups and the terminal functional groups are chemically orthogonal to one another. This family also covers mixtures of oxazoline monomers on the same polymer backbone e.g., ethyl oxazoline and pentynyl oxazoline. This family covers every class of molecule attached to POZ, including but not limited to small molecules, proteins, oligonucleotides, and lipids where the attached molecule can be a therapeutic, diagnostic, or targeting molecule. The family also covers such poly(oxazoline) polymers linked to various target molecules, such as therapeutic agents and targeting agents and of using such conjugates in the treatment or diagnosis of cancer:

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
US	Utility	Granted	Jan-12-2009	12/744,472	Feb-07-2012	8,110,651	3-21-2029
US	Utility	Granted (CIP of '651)	May-25-2010	12/787,241	Jan-24-2012	8,101,706	3-20-2029
US	Utility	Granted (DIV of '706)	Jan-23-2012	13/356,552	Aug-06-2013	8,501,899	1-29-2029
US	Utility	Granted (CON of '899)	Feb-06-2012	13/367,128	Oct-27-2015	9,169,354	1-12-2029
US	Utility	Granted (CON of '354)	Jul-08-2016	15/205,671	Jan-01-2019	10,166,294	1-12-2029
US	Utility	Granted (CON of '294)	Dec-28-2018	16/235,936	Jan-04-2022	11,213,588	1-12-2029
US	Utility	Granted (CON of '588)	Jan-04-2022	17/568,042	Mar-12-2024	11,925,689	1-29-2029

Table of Contents

US	Utility	Abandoned	Mar-11-2024	18/601,960				
China	Utility	Granted	Jan-12-2009	200980106276.5	Dec-12-2012		1098857	1-12-2029
Japan	Utility	Granted	Jan-12-2009	2010-542410	Apr-04-2014		5,514,736	1-12-2029
Korea (South)	Utility	Granted	Jan-12-2009	10-2010-7017208	Jan-20-2015		10-1486449	1-12-2029
Belgium	Utility	Granted	Jan-12-2009	09701187.8	Sep-04-2013		2,235,090	1-12-2029
Belgium	Utility	Granted	Jan-12-2009	13181892.4	Mar-23-2016		2,669,313	1-12-2029
Belgium	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029
Switzerland	Utility	Granted	Jan-12-2009	09701187.8	Sep-04-2013		2,235,090	1-12-2029
Switzerland	Utility	Granted	Jan-12-2009	13181892.4	Mar-23-2016		2,669,313	1-12-2029
Switzerland	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029
Germany	Utility	Granted	Jan-12-2009	09701187.8	Sep-04-2013		2,235,090	1-12-2029
Germany	Utility	Granted	Jan-12-2009	13181892.4	Mar-23-2016		2,669,313	1-12-2029
Germany	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029
Denmark	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029
France	Utility	Granted	Jan-12-2009	09701187.8	Sep-04-2013		2,235,090	1-12-2029
France	Utility	Granted	Jan-12-2009	13181892.4	Mar-23-2016		2,669,313	1-12-2029
France	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029
United Kingdom	Utility	Granted	Jan-12-2009	09701187.8	Sep-04-2013		2,235,090	1-12-2029
United Kingdom	Utility	Granted	Jan-12-2009	13181892.4	Mar-23-2016		2,669,313	1-12-2029
United Kingdom	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029
Netherlands	Utility	Granted	Jan-12-2009	09701187.8	Sep-04-2013		2,235,090	1-12-2029
Netherlands	Utility	Granted	Jan-12-2009	13181892.4	Mar-23-2016		2,669,313	1-12-2029
Netherlands	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029
Sweden	Utility	Granted	Jan-12-2009	09701187.8	Sep-04-2013		2,235,090	1-12-2029
Sweden	Utility	Granted	Jan-12-2009	13181892.4	Mar-23-2016		2,669,313	1-12-2029
Sweden	Utility	Granted	Jan-12-2009	16154587.6	Jul-19-2017		3,042,922	1-12-2029

SER-08 family: “Poly(oxazoline) with Inert Terminating Groups, Polyoxazolines Prepared from Protected Initiating Groups and Related Compounds” (M. D. Bentley *et al.*)

This family of patents relates to linear, branched, multi-arm and pendant POZ™ with initiating functional groups. This patent family also covers compositions of POZ™ conjugates of phospholipids and glycolipids for use in making lipid nanoparticles (LNP):

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
China	Utility	Granted	Jul-10-2009	200980135512.6	Jun-25-2014	102149749B	7-10-2029
Japan	Utility	Granted	Jul-10-2009	2011-517658	Nov-07-2014	5,642,673	7-10-2029
Korea (South)	Utility	Granted	Jul-10-2009	10-2011-7003132	Aug-04-2016	10-167334	7-10-2029
US	Utility	Granted	Jul-10-2009	13/003,306	Nov-11-2014	8,883,211	3-23-2031
US	Utility	Granted	Nov-10-2014	14/537,516	Mar-15-2016	9,284,411	7-10-2029

SER-16 Family: “Subcutaneous Delivery of Poly(oxazoline) Conjugates” (R. W. Moreadith *et al.*)

This family of patents provides for poly(oxazoline) conjugates of dopamine agonists and subcutaneous delivery of these conjugates for treatment of conditions related to dopamine insufficiency, such as Parkinson’s disease. In particular, this family includes claims to conjugates containing rotigotine, *i.e.*, SER-214. The ’633 patent (US) has broader claims and would cover other molecules administered as subcutaneous injections, including but not limited to SER-226/227, SER-228/229 SER-232 and SER-252.

Table of Contents

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
US	Utility	Granted	Jun-15-2012	13/524,994	Feb-26-2013	8,383,093	6-15-2032
US	Utility	Granted	Feb-22-2013	13/774,304	Dec-03-2013	8,597,633	6-15-2032
US	Utility	Granted	Jun-29-2016	15/197,336	Jun-11-2019	10,314,837	6-15-2032
US	Utility	Granted	Jun-10-2019	16/436,590	Jan-18-2022	11,224,595	6-15-2032
US	Utility	Granted	Apr-05-2017	15/480,122	Oct-01-2019	10,426,768	6-15-2032
US	Utility	Granted	Sep-30-2019	16/588,761	Apr-12-2022	11,298,350	6-15-2032
US	Utility	Granted	Apr-11-2022	17/717,666	Apr-2-2024	11,944,618	6-15-2032
Canada	Utility	Granted	Nov-01-2012	2,854,361	Aug-11-2020	2,854,361	11-1-2032
Japan	Utility	Granted	Nov-01-2012	2014-540093	Jul-21-2017	6,177,787	11-1-2032
Japan	Utility	Granted	Jul-11-2017	2017-135578	Apr-26-2019	6,517,281	11-1-2032
Japan	Utility	Granted	Apr-16-2019	2019-077583	May-12-2021	6,883,605	11-1-2032
Korea (South)	Utility	Granted	Nov-01-2012	10-2014-7014846	May-21-2020	10-2115862	11-1-2032
Belgium	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032
Switzerland	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032
Germany	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032
Denmark	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032
United Kingdom	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032
France	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032
Netherlands	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032
Sweden	Utility	Granted	Nov-01-2012	12846647.1	Oct-09-2019	2,773,379	11-1-2032

SER 18 Family: “Polyoxazoline Antibody Drug Conjugates” (R. W. Moreadith *et al.*)

This patent family describes and claims polymer-ADCs to treat human disease. They provide a large DAR.

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
China	Utility	Granted	Jul-31-2015	201580052259.3	Mar-13-2020	3716373	7-31-2035
Japan	Utility	Granted	Jul-31-2015	2017-505548	May-15-2020	6,704,900	7-31-2035
US	Utility	Granted	Jul-31-2015	14/815,718	Sep-11-2018	10,071,168	7-31-2035
US	Utility	Granted	Sep-10-2018	16/126,798	Jul-21-2021	11,065,340	7-31-2035

SER 22 Family: “Cleavable Conjugates of Catechol Compounds and Water-Soluble Polymers and Methods of Treatment Using the Same” (M. D. Bentley *et al.*)

This family covers conjugates including a water-soluble polymer linked to a compound including a catechol moiety via a cleavable linkage, wherein the cleavable linkage is formed between the water-soluble polymer and a first phenolic hydroxyl group of the catechol moiety and a second phenolic hydroxyl group of the catechol moiety is linked to a blocking group. The rate of hydrolytic release of the compound including the catechol moiety is controlled, at least in part, through structure or design of the blocking group on the second phenolic hydroxyl group of the catechol moiety such that the rate of hydrolytic release of the compound including the catechol moiety can be tuned through structural design of the group on the second phenolic hydroxyl group of the catechol moiety.

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
Australia	Utility	Granted	Jul-27-2019	2019309523	Jan-2-2025	2019309523	7-27-2039
Australia	Utility	Pending	Dec-18-2024	2024278567			
Canada	Utility	Pending	Jul-27-2019	3,107,317			
China	Utility	Pending	Jul-27-2019	CN201980063964			

Table of Contents

Hong Kong	Utility	Published	Jan-26-2022	62022045767.0				
Europe	Utility	Pending	Jul-27-2019	19841823.8				
Israel	Utility	Pending	Jul-27-2019	280364				
Japan	Utility	Pending	Jul-27-2019	2021-504354	Jan-6-2025	7614086	7-27-2039	
Korea (South)	Utility	Pending	Jul-27-2019	10-2021-7006020				
US	Utility	Granted	Jan-27-2021	17/263,723	Sept-26-2023	11,766,432	7-27-2039	
US	Utility	Pending	Sept-19-2023	18/370,069				

SER 23 Family: “Polyoxazoline-Drug Conjugates with Novel Pharmacokinetic Properties” (J. M. Harris *et al.*)

This family relates to all POZ polymer conjugates of cannabinoids, including and not limited to SER 228, SER 229, SER 232 and POZ-cannabinoids of cannabidivarin, cannabigerol and cannabichromene.

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
World Intellectual Property Org. (WIPO)	Utility	Pending	Jun-29-2020	PCT/US2020/040140			
Australia	Utility	Pending	Dec-23-2021	2020301324			
Canada	Utility	Pending	Dec-21-2021	3,144,774			
China	Utility	Pending	Jun-29-2020	CN202080060438			
Europe	Utility	Pending	Dec-20-2021	20830744.7			
Israel	Utility	Pending	Dec-21-2021	28921721			
Japan	Utility	Pending	Dec-24-2021	2021576959			
Korea	Utility	Pending	Jan-27-2022	10-2022-7003221			
New Zealand	Utility	Pending	Jun-29-2020	783931			
US	Utility	Pending	Dec-21-2021	17/621,613			
US	Utility	Pending	May-3-2024	18/654,735			
US	Utility	Pending	May-3-2024	18/654,902			

SER 24 family: “Polyoxazoline-lipid Conjugates and Lipid Nanoparticles and Pharmaceutical Compositions Including Same” (J. M. Harris *et al.*)

This family relates to the chemical synthesis of POZ polymer conjugates of lipids that may be used to make lipid nanoparticles. The patent application discloses multiple different architectures of POZ, including but not limited to releasable linkages, stable linkages, therapeutic oligonucleotides (DNA, mRNA) and use in, and manufacture of, vaccines for infectious diseases and various therapeutic approaches.

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
US	Utility	Granted	Feb-04-2022	17/665,190	Feb-25-2025	12233132	5-23-2042
US	Utility	Pending	Nov-7-2023	18/387,528			
Canada	Utility	Pending	Jul-24-2023	3206128			
China	Utility	Pending	Sept-28-2023	10000513331914			
Japan	Utility	Pending	Aug-08-2023	2023-547812			
Israel	Utility	Pending	Jul-26-2023	304773			
Europe	Utility	Pending	Aug-24-2023	22753169.6			
Australia	Utility	Pending	Jul-24-2023	2022219902			

Table of Contents

New Zealand	Utility	Pending	Jul-25-2023	802213					
South Korea	Utility	Pending	Sept-6-2023	10-2023-7030341					
Hong Kong		Published	May 6, 2024	62024090980.9					

SER-25: “Targeting of Antigen-Presenting Cells by Nanoparticles Containing POZ-Lipid Conjugates” (R. Moreadith *et al.*)

We co-own, along with Georgia Tech Research Corporation, a patent application related to a method of targeting antigen-presenting cells with LNPs including polyoxazoline-lipid conjugates (or pharmaceutical compositions including such LNPs).

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
US	Utility	Pending	Dec-21-2023	18/391,869			
PCT	Utility	Pending	Dec-21-2023	PCT/US23/85316			

SER-26: “Poly(oxazoline) Conjugates with Pendant Cationic Groups and Lipid Nanoparticles Including Same” (Moreadith *et al.*)

Serina has begun to cultivate a patent family related to polyoxazoline (POZ) conjugates with pendent and terminal cationic groups (cationic POZ) and methods of synthesis. In addition, the present disclosure relates to lipid nanoparticles (LNPs) including cationic POZ and pharmaceutical compositions including such LNPs. LNPs incorporating oligonucleotides such as mRNA, DNA, saRNA and siRNA for delivery into living cells is also contemplated.

Country	Type	Status	Application Date	Application Number	Grant Date	Grant Number	Expiration Date
US	Utility	Pending	Jun-14-2024	18/743,721			
PCT	Utility	Pending	Jun-14-2024	PCT/US24/34074			

Competition

We face substantial competition from multiple sources, including large and specialty pharmaceutical, biopharmaceutical, and biotechnology companies, academic research institutions and governmental agencies, and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development, and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of drug delivery generally and, furthermore, within the treatment of diseases in which we expect to compete in the future.

In addition to the current treatments for patients, numerous commercial and academic preclinical studies and clinical trials are being undertaken by many parties to assess novel technologies and product candidates in the field of CNS disorders. Results from these studies and trials have fueled increasing levels of interest in the CNS field.

Several companies are in the business of developing and marketing polymer-modified therapeutics, with the majority using PEG polymers. The covalent attachment of PEG to therapeutic agents, termed PEGylation, is a well-established and clinically proven drug delivery approach to improve the PK and pharmacodynamics of drugs. Specifically, PEGylation can improve the parent drug’s solubility, extend our circulation time, and reduce our immunogenicity, with minimal undesirable properties. PEGylation technology has been applied to various therapeutic modalities or payloads including small molecules, aptamers, peptides, and proteins, leading to over 30 FDA approved PEGylated drugs currently in use and many investigational PEGylated agents under clinical trials.

Government Regulation

Our operations and activities are subject to extensive regulation by numerous government authorities in the U.S., Europe and other countries. In the United States, Europe and other countries, our products are subject to rigorous regulations governing their testing, manufacture, labeling, storage, record keeping, approval, and advertising and promotion. As a result of these regulations, product development and product approval processes are very expensive and time consuming. The regulatory requirements applicable to drug and biologic development, approval, and marketing are subject to change. In addition, regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA or comparable ex-U.S. regulations, guidance or interpretations will change.

United States Government Regulation

New Drug Application and Biologics License Application Approval Processes

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices (“GLP”), and other applicable regulations;
- submission to the FDA of an Investigational New Drug Application (“IND”), which must become effective before clinical trials in the United States may begin;
- performance of adequate and well-controlled clinical trials according to Good Clinical Practices (“GCP”), and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a New Drug Application (“NDA”) or a Biologics License Application (“BLA”);
- satisfactory completion of a pre-approval FDA inspection of the manufacturing facility or facilities at which the product will be produced to assess compliance with cGMP; and
- FDA review and approval of the NDA or BLA.

Once a drug or biologic is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal pharmacology and toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND, which seeks FDA approval to test the drug or biologic in humans. Preclinical or nonclinical testing typically continues even after the IND is submitted.

If the FDA accepts the IND, the drug or biologic can then be studied in human clinical trials to determine if the product candidate is safe and effective. Clinical trials typically involve three separate phases that often overlap, can take many years and are expensive. These three phases, which are subject to considerable regulation, are as follows:

- *Phase 1.* The drug or biologic initially is introduced into a limited number of healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some drugs or biologics for severe or life-threatening diseases, such as cancer, especially when the drug or biologic may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* Clinical trials are next initiated in a limited patient population with the specified disease or condition the drug or biologic is intended to treat to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug or biologic candidate for the disease or condition it is intended to treat and to determine dosage tolerance and optimal dosage.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the

[Table of Contents](#)

overall risk-benefit ratio of the drug or biologic and provide an adequate basis for regulatory approval and product labeling.

It is possible that Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may, at any time during the initial 30-day IND review period or while clinical trials are ongoing under the IND, impose a partial or complete clinical hold or suspend a clinical trial at any time for a variety of reasons, including a finding that the healthy volunteers or patients are being exposed to an unacceptable health risk. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently in other situations, and the occurrence of serious adverse events must also be reported. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the www.clinicaltrials.gov website.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

The results of drug or biologic development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug or biologic, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the drug or biologic. The FDA reviews each NDA or BLA submitted to ensure that it is sufficiently complete for substantive review before it accepts it for filing. It may request additional information rather than accept an NDA or BLA for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA reviews an NDA or BLA to determine, among other things, whether a drug or biologic is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the drug or biologic's identity, strength, quality and purity. The FDA may refer the NDA or BLA to an advisory committee for review and recommendation as to whether the NDA or BLA should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the drug or biologic is manufactured and tested. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

The FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, submission of promotional materials, restrictions on direct-to-consumer advertising or commitments to conduct additional research post-approval. The FDA will issue a complete response letter if the agency decides not to approve the NDA or BLA in its present form.

Expedited Review and Approval

The FDA has developed a number of distinct approaches to make new drugs or biologics available as rapidly as possible in cases where there is no available treatment or there are advantages over existing treatments.

The FDA may grant "accelerated approval" to products that have been studied for their safety and effectiveness in treating serious illnesses and that provide meaningful therapeutic benefit to patients over existing treatments. For accelerated approval, the product must have an effect on a surrogate endpoint or an intermediate clinical endpoint that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe the clinical benefit. These studies are known as "confirmatory trials." Approval of a drug may be withdrawn, or the labeled indication of the drug changed if these trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug or biologic.

The FDA may grant "fast track" status to products that treat serious diseases or conditions and demonstrate the potential to address an unmet medical need. Fast track is a process designed to facilitate the development and expedite the review of such products by providing, among other things, more frequent meetings with the FDA to discuss the product's development plan and rolling review, which allows submission of individually completed sections of an NDA or BLA for FDA review before the entire submission is completed. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval.

[Table of Contents](#)

“Breakthrough Therapy” designation is a process designed to expedite the development and review of drugs or biologics that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over available therapy on one or more clinically significant endpoints. Breakthrough Therapy designation provides all of the benefits of fast-track designation in addition to robust FDA-sponsor interaction and communication to help to identify the most efficient and expeditious path for clinical development while minimizing the number of patients placed in ineffective control regimens.

“Regenerative Medicine Advanced Therapy” (“RMAT”) designation is a process created by the 21st Century Cures Act in December 2016. A product is eligible for RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious disease or condition, and if preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of RMAT designation include the benefits available to breakthrough therapies, including potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

The FDA may grant “priority review” status to a product that, if approved, would provide significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Priority review is intended to reduce the time it takes for the FDA to review an NDA or BLA, with the goal to take action on the application within six months from when the application is filed, compared to ten months for a standard review.

Manufacturing Quality Control

Among the conditions for NDA or BLA approval is the requirement that the prospective manufacturer’s quality control and manufacturing procedures continually conform with cGMP. Manufacturers must devote substantial time, money and effort in the areas of production, quality control, and quality assurance to maintain cGMP compliance. Material changes in manufacturing equipment, location, or process, may result in additional regulatory review and approval. The FDA, and other regulatory agencies, conduct periodic visits to inspect equipment, facilities, and processes following the initial approval of a product. If a manufacturing facility is not in substantial compliance with the applicable regulations and requirements imposed when the product was approved, regulatory or judicial enforcement action may be initiated, which may include a warning letter, suspension of manufacturing, product seizure, or an injunction against shipment of products from the facility and/or recall of products previously shipped. We rely, and expect to continue to rely, on third parties for the production of our products. Future FDA, state, and foreign inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt manufacture or distribution of our products or require substantial resources to correct.

Post-approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or complete withdrawal of the product from the market. In addition, the sponsor of an approved drug in the United States may not promote that drug for unapproved, although a physician may prescribe a drug for an unapproved use in accordance with the practice of medicine. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of unapproved uses, as well as false or misleading promotion. Further, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing, including Phase 4 trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the product;
- providing the FDA with updated safety and efficacy information;

[Table of Contents](#)

- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes;
- complying with certain electronic records and signature requirements; and
- complying with FDA promotion and advertising requirements.

Failure to comply with the applicable United States requirements at any time during the drug or biologic development process, approval process or after approval, may subject us or our collaborators to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- restrictions on marketing or manufacturing of the product;
- safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve or delay in review of pending applications;
- withdrawal of an approval or the implementation of limitations on a previously approved indication for use;
- imposition of a clinical hold, a risk evaluation and mitigation strategy (“REMS”) or other safety-related limitations;
- warning letters or “untitled letters;”
- product seizures, recalls, or detentions, or refusal to permit the import or export of products;
- total or partial suspension of production or distribution;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or
- injunctions, fines, disgorgement, refusals of government contracts, or civil or criminal penalties.

United States Patent Term Restoration and Regulatory Exclusivity

Upon approval, products may be entitled to certain kinds of exclusivity under applicable intellectual property and regulatory regimes. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The length of the patent extension is roughly based on 50 percent of the period of time from the filing of an IND for a compound to the submission of the NDA for such compound, plus 100 percent of the time period from NDA submission to regulatory approval. The extension, however, cannot exceed five years and the patent term remaining after regulatory approval cannot exceed 14 years.

If the FDA approves a drug product that contains a new chemical entity not previously approved, the product is typically entitled to five years of non-patent regulatory exclusivity. Other products may be entitled to three years of exclusivity if approval was based on the FDA’s reliance on new clinical studies essential to approval submitted by the NDA applicant.

Biologics are also entitled to exclusivity under the Biologics Price Competition and Innovation Act (the “BPCIA”), which was passed as Title VII to the ACA. The law provides a pathway for approval of products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity, the period of time during which an innovator’s clinical data cannot be used by other companies, from the time of first licensure of the product, and 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. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. Biologics are also eligible for orphan drug

[Table of Contents](#)

exclusivity, as discussed below. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability prior to the approval of the biosimilar. There have been ongoing federal legislative and administrative efforts as well as judicial challenges seeking to repeal, modify or invalidate some or all of the provisions of the ACA. While none of those efforts have focused on changes to the provisions of the ACA related to the biosimilar regulatory framework, if the ACA is repealed, substantially modified, or invalidated, it is unclear what, if any, impact such action would have on biosimilar regulation. If the NDA or BLA applicant studies the product for use by children, the FDA may grant pediatric exclusivity, which extends by 180 days each existing exclusivity (patent and regulatory) related to the product.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 people in the United States.

If a drug or biologic that has orphan drug designation subsequently receives the first FDA approval for that drug or biologic for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years following marketing approval, except in certain very limited circumstances, such as if the later product is shown to be clinically superior to the orphan product. Orphan drug exclusivity, however, also could block the approval of our products for seven years if a competitor first obtains approval of the same drug, as defined by the FDA, for the same disease or condition for which we were seeking approval.

We may pursue orphan drug designation for certain of our future product candidates. Even if we obtain orphan drug designation for a product candidate, we may not be the first to obtain marketing approval for the product candidate for any particular orphan indication due to the uncertainties associated with developing novel therapies. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because orphan drug exclusivity does not prevent different drugs from being approved for the same condition. Moreover, orphan drug exclusivity may not prevent the approval of another sponsor's product that is considered to be the same drug for a different disease or condition, even where such product could be prescribed for an unapproved indication that is protected by orphan drug exclusivity. Even after an orphan drug is approved, regulators may subsequently approve the same drug made by another manufacturer for the same condition if the regulator concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

Foreign Regulation

We conduct clinical trials and market our products in numerous jurisdictions outside the U.S. Most of these jurisdictions have clinical trial, product approval and post-approval regulatory processes that are similar in principle to those in the U.S. Thus, whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we can commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under the European Union regulatory system, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for orphan medicines, medicines produced by biotechnology, and those medicines intended to treat AIDS, cancer, neurodegenerative disorders, or diabetes, and optional for those medicines that are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. In addition to the centralized procedure, the European Union also has a nationalized procedure, which requires a separate application to and approval determination by each country; a decentralized procedure, whereby applicants submit identical applications to several countries and receive simultaneous approval; and a mutual recognition procedure, where applicants submit an application to one country for review and other countries may accept or reject the initial decision.

Despite the U.K. formally withdrawing from the European Union on January 31, 2020, a number of European Union regulations were retained in U.K. law. The U.K. government has communicated an intent to remove or replace some of

these European Union provisions, which may increase some regulatory divergence between the U.K. and the European Union

Regulations Concerning Reimbursement

Sales of products depend, to a large degree, on the extent to which products will be reimbursed by third-party payors, such as government health programs, commercial insurance, and managed health care organizations. Increasingly, these third-party payors are becoming stricter in the ways they evaluate and reimburse medical products and services. Additionally, the containment of health care costs has become a priority of many governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign 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 limit our revenues. Decisions by third-party payors to not cover a product could reduce physician usage of the product.

There are a number of governmental pricing programs in the United States, including the Medicaid Drug Rebate program, Medicare. Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Under the Medicaid Drug Rebate program, companies are required to pay a rebate to each state Medicaid program for their covered outpatient drugs, which includes select inpatient drugs for which there is “direct reimbursement.” Medicaid rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid and Medicare programs.

Any company that participates in the Medicaid Drug Rebate program also must participate in the 340B drug pricing program (the “340B program”), and the Federal Supply Schedule (“FSS”) pricing program. The 340B program, which is administered by the Health Resources and Services Administration, requires participating companies to agree to charge statutorily defined “covered entities” no more than the 340B “ceiling price” for covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula, which is based on pricing data calculated under the Medicaid Drug Rebate Program. The FSS pricing program, which is administered by the Department of Veterans Affairs (“VA”), also requires participating companies to extend discounted prices to the VA, Department of Defense, Coast Guard, and Public Health Service. Similar to the 340B program, FSS prices are calculated utilizing pricing data reported by us to the VA on a quarterly and annual basis.

The Medicare program includes “Part A” that generally covers certain hospital services for eligible beneficiaries. In general, Part A covers inpatient hospital services, skilled nursing, and hospice care. Most individuals are enrolled in Medicare Part A upon reaching age 65 (although other individuals qualify for Part A, including those receiving services for end stage renal disease). Prescription drugs that are used as part of an inpatient hospital stay will be covered by Medicare Part A, and these products typically are paid as part of a bundled or composite rate (e.g., diagnosis related group).

The Medicare Part D program provides a voluntary prescription drug benefit to Medicare beneficiaries. Under “Part D,” Medicare beneficiaries may enroll in prescription drug plans offered by private entities, which provide coverage of outpatient prescription drugs such as our acute pain and CF medicines. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutics committee. U.S. government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval.

Private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. As a result, any reduction in payment that results from Part D reimbursement may result in a similar reduction in payments from non-governmental payors for our products. Additionally, private payors, including health maintenance organizations and pharmacy benefit managers in the U.S., are adopting more aggressive utilization management techniques, and are increasingly applying restrictive plan designs that can impact patients and manufacturers and they continue to push for significant discounts and rebates from manufacturers. As a consequence, these payors may not cover or adequately reimburse for use of our products or may do so at levels that disadvantage them relative to competitive products.

The U.S. government has shown significant interest in implementing cost-containment programs for medicines and has enacted reforms at the state and federal level designed to, among other things, modify prescription drug reimbursement amounts and methodologies, and otherwise control health care costs. The Patient Protection and Affordable Care Act

[Table of Contents](#)

(“ACA”) was enacted in March 2010 and was designed to expand coverage for the uninsured while at the same time containing overall health care costs. With regard to pharmaceutical products, among other things, the ACA was designed to expand and increase industry rebates for drugs covered under Medicaid programs, impose an annual fee on branded pharmaceutical manufacturers, subject biological products to potential competition by lower-cost biosimilars, and make changes to the coverage requirements under the Medicare Part D program. Additionally, in August 2022, the Inflation Reduction Act (“IRA”) was enacted, establishing a Medicare Drug Price Negotiation Program, a Medicare inflationary rebate, and a redesign of the Part D benefit structure. Certain drugs are excluded from the IRA negotiation program. Nevertheless, other elements of the IRA may have a material impact on companies in our industry, including the redesign of the Part D benefit and the new Manufacturer Discount Program, which will require manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. Under the Non-Opioids Prevent Addiction in the Nation (“NOPAIN”) Act, CMS reimbursement for novel, oral, non-opioids will include an add-on payment when the drug is used in the hospital outpatient and ambulatory surgery center settings.

We anticipate that the U.S. government will continue to engage in activities seeking to address drug pricing and reimbursement. Furthermore, certain states have enacted laws establishing Prescription Drug Affordability Boards (“PDABs”). Some state PDABs, including those in Colorado, Maryland, Washington, and Minnesota, either have the authority or have defined a pathway pursuant to which they may be granted the authority to establish upper payment limits for prescription drugs. In certain states, there is pending litigation that would establish a PDAB or expand the authority of an existing PDAB.

In Europe and other foreign jurisdictions, the success of our products depends largely on obtaining and maintaining government reimbursement, because patients are generally unable to access prescription pharmaceutical products that are not reimbursed by their governments. In some countries, such as Germany, commercial sales of a new product may begin while pricing and reimbursement terms are under discussion. In other countries, a company must complete reimbursement negotiations prior to the commencement of commercial supply of the pharmaceutical product. The requirements governing drug pricing vary widely country-by-country and region-by-region. For example, the member states of the European Union can restrict the range of drugs for which their national health insurance systems provide reimbursement and can control the prices of prescription drugs. In addition, many ex-U.S. government payors require companies to provide health economic assessments of products, which are evaluated by government agencies set up for this purpose. A member state may approve a specific price for the drug, or it may instead adopt a system of direct or indirect controls on the total amount of money that a company may receive for supply of a drug. Countries also may consider increasing mandatory discounts over time in an attempt to manage increased demands on healthcare budgets. Reimbursement discussions in foreign countries often result in a reimbursement price that is lower than the net price that companies can obtain for the product in the U.S. In addition, reimbursement discussions may take a significant period of time resulting in commercialization delays. In some countries where reimbursement has not yet been obtained, or where there are a limited number of eligible people and our medicines or therapies are unregistered, the governments of such countries may agree to purchase our medicines and therapies on an unlicensed and/or named patient basis. Reimbursement for our products cannot be assured because a country or region may only provide for reimbursement on terms that we do not deem adequate. Further, many ex-U.S. governments have introduced or are in the process of introducing legislation focusing on cost containment measures in the pharmaceutical industry. The impact of these laws where finalized, the final form of laws under consideration, and their relevant practical application, are unknown at this time, but may lead to lower prices, paybacks, or other forms of discounts or special taxes.

Other Regulations

Pharmaceutical companies are also subject to various laws pertaining to healthcare “fraud and abuse,” including the federal Anti-Kickback Statute (“AKS”), the False Claims Act (“FCA”), and other state and federal laws and regulations. In the U.S., the Anti-Kickback Statute generally makes it illegal to knowingly and willfully solicit, offer, receive or pay any remuneration in return for or to induce the referral of business, including the purchase or prescription of a particular drug that is reimbursed by a state or federal health care program. The FCA prohibits knowingly and willingly presenting or causing to be presented for payment to third-party payors (including Medicare and Medicaid), any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under the FCA may also arise when a violation of certain laws or regulations related to the underlying products (e.g., violations regarding improper promotional activity, manufacturing regulations, or

[Table of Contents](#)

unlawful payments) contributes to the submission of a false claim. If we were subject to allegations concerning, or convicted of violating, these laws, our business could be harmed.

Laws and regulations also have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers, require manufacturers to adopt certain compliance standards or require disclosure to the government and public of such interactions. The laws include U.S. federal and state “sunshine” provisions. The federal sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments and other transfers of value made to physicians, physicians assistants, advanced practice registered nurses, and teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain requirements that are subject to interpretation. Outside the U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

Our collection and use of personal data as part of our business activities is subject to various privacy and data security laws and regulations, including oversight by various regulatory or other governmental bodies, in the U.S., European Union, U.K., Canada, Australia, Brazil, Saudi Arabia and other jurisdictions. Such laws and regulations have the potential to affect our business materially, continue to evolve and increasingly are being enforced.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export and use and disposal of hazardous or potentially hazardous substances are or may be applicable to our activities.

Human Capital

As of December 31, 2025, we had sixteen full time employees. We do not have any employees represented by a labor union or covered under a collective bargaining agreement.

Facilities

Our current headquarters located in Huntsville, Alabama is comprised of approximately 7,600 square feet of office and laboratory space. The lease term is two years for the office space and five years for the laboratory space. The lease termination date is October 31, 2028 for the office space and January 31, 2028 for the laboratory space.

Investor Information

Financial and other information about us is available on our website at <https://www.serinatx.com/>. We make available on our website, free of charge, copies of our Annual Report 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 U.S. Securities and Exchange Commission (the "SEC"). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected without charge at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

Item 1A. Risk Factors

Investing in our securities involves risks. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Report, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes, before deciding whether to purchase any of our securities. Our business, results of operations, financial condition, and prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of these risks actually occur, our business, results of operations, financial condition, and prospects could be materially and adversely affected. Unless otherwise indicated, references in these risk factors to our business

[Table of Contents](#)

being harmed will include harm to our business, reputation, brand, financial condition, results of operations, and prospects. In such event, the market price of our securities could decline, and you could lose all or part of your investment.

Investing in our securities involves risks. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Report, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes, before deciding whether to purchase any of our securities. Our business, results of operations, financial condition, and prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of these risks actually occur, our business, results of operations, financial condition, and prospects could be materially and adversely affected. Unless otherwise indicated, references in these risk factors to our business being harmed will include harm to our business, reputation, brand, financial condition, results of operations, and prospects. In such event, the market price of our securities could decline, and you could lose all or part of your investment.

Risks Related to Our Operating History, Financial Position and Capital Requirements

We have a history of operating losses that are expected to continue for the foreseeable future, and we are unable to predict the extent of future losses, or whether we will generate significant revenues or achieve or sustain profitability.

We have focused on research and product development and have not generated any revenues to date from product sales. Additionally, we expect to continue to incur operating losses for the foreseeable future. These operating losses have adversely affected, and are likely to continue to adversely affect, our working capital, total assets, and stockholders’ deficit.

Because we are an early-stage company, our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations.

We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

We are dependent on obtaining, and will continue to pursue, necessary funding from outside sources, including obtaining additional funding from the issuance of securities in order to continue our operations. Without adequate funding, we may not be able to meet our financial obligations.

We have not demonstrated an ability to perform the functions necessary for the successful commercialization of any products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

- continuing to undertake preclinical and clinical development;
- engaging in the development of product candidate formulations and manufacturing processes;
- interacting with the applicable regulatory authorities and pursuing other required steps for regulatory approval;
- engaging with payors and other pricing and reimbursement authorities;
- submitting marketing applications to, and receiving approval from, the applicable regulatory authorities; and
- manufacturing the applicable products and product candidates in accordance with regulatory requirements and, if ultimately approved, conducting sales and marketing activities in accordance with health care, FDA and similar foreign regulatory authority laws and regulations.

We have a limited operating history and expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

[Table of Contents](#)

Our operations to date have been primarily limited to organizing and staffing our company, developing and securing our proprietary technology and preclinical and clinical development of our product candidates. We have not yet successfully completed all clinical trial phases for any of our product candidates, manufactured our product candidates at commercial scale or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates, if approved.

Our financial condition has varied significantly in the past and will continue to fluctuate from quarter to quarter or year to year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this annual report and also include, among other things:

- our ability to obtain additional funding to develop our product candidates;
- our ability to conduct and complete nonclinical studies and clinical trials,
- delays in the commencement, enrollment, and timing of clinical trials;
- the success of our nonclinical studies and clinical trials through all phases of development;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions;
- potential toxicity and/or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved products, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;
- our ability to establish or maintain partnerships, collaborations, licensing or other arrangements;
- market acceptance of our product candidates, if approved;
- competition from existing products, new products or new therapeutic approaches that may emerge;
- the ability of patients or health care providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary POZ technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business; and
- potential product liability claims.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We need additional financing to execute our operating plan and continue to operate as a going concern.

As required under Accounting Standards Update 2014-15, Presentation of Financial Statements-Going Concern (ASC 205-40), we have the responsibility to evaluate whether conditions and/or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date the financial statements are issued. Based on our most recent projected cash flows, we believe that our cash and cash equivalents would not be sufficient to satisfy our anticipated operating and other funding requirements for the next twelve months from December 31, 2025. These factors raise substantial doubt regarding our ability to continue as a going concern. In addition, the report of our

[Table of Contents](#)

independent registered public accountant accompanying our audited consolidated financial statements included elsewhere in this annual report contains a qualification to such effect.

We have incurred operating losses and negative cash flows since inception and had an accumulated deficit of approximately \$63.5 million as of December 31, 2025. We expect to continue to incur operating losses and negative cash flows. Our operations have consumed substantial amounts of cash. We will require substantial additional funds to support our continued research and development activities, including the anticipated costs of nonclinical studies and clinical trials, regulatory approvals, and potential commercialization. Additionally, our estimates on future financial needs may be based on assumptions that prove to be wrong, and we may spend our available financial resources much faster than we expect. Because we expect to continue to experience operating losses, our ability to continue as a going concern is subject to our ability to obtain necessary capital from outside sources, including obtaining additional capital from the sale of our capital stock or other equity securities or assets, obtaining additional loans from financial institutions or investors, and entering into collaborative research and development arrangements or licensing some or all of our patents and know-how to third parties while retaining a royalty and other contingent payment rights related to the development and commercialization of products covered by the licenses. Our continued operating losses and the risks associated with the development of our product candidates and technologies have increased the difficulty in obtaining such capital, and there can be no assurances that we will be able to obtain such capital on favorable terms or at all. Furthermore, geopolitical instability, including the ongoing military conflicts between the United States and Iran, Russia and Ukraine, and Israel and Hamas, as well as the impact of inflationary pressures and resulting rise in interest rates, on global financial markets could make the terms of any available financing less attractive to us and more dilutive to our existing stockholders. If we are unable to raise additional capital, we will have to delay, curtail, or eliminate one or more of our research and development programs or ultimately not be able to continue as a going concern. Additionally, raising additional capital may cause dilution to our stockholders.

We have never generated revenue from product sales and may never become profitable.

Our ability to generate product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our current and future product candidates. We do not anticipate generating product sales for the next several years, if ever.

Our product candidates will require additional clinical, manufacturing, and non-clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we generate any product sales. We cannot guarantee that we will meet our timelines for our development programs, which may be delayed or not completed for a number of reasons. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators', ability to successfully:

- complete research and obtain favorable results from nonclinical and clinical development of our current and future product candidates, including addressing any clinical holds that may be placed on our development activities by regulatory authorities;
- seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials, as well as their manufacturing facilities;
- launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualify for coverage and establish adequate reimbursement by government and third-party payors for any of our product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;
- establish and maintain supply and manufacturing capabilities internally or with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval;

[Table of Contents](#)

- obtain market acceptance of current or any future product candidates as viable treatment options and effectively compete with other therapies to establish market share;
- maintain a continued acceptable safety and efficacy profile of our product candidates following launch;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and perform our obligations in such collaborations;
- maintain, protect, enforce, defend, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- avoid and defend against third-party interference, infringement, and other intellectual property claims; and
- attract, hire, and retain qualified personnel.

Even if one or more of our current and future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. If we are required to conduct additional clinical trials or other testing of our product candidates that we develop beyond those that we currently expect, 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, not obtain marketing approval at all, or obtain more limited approvals. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

Risks Related to the Development of Our Products

Our product candidates are at an early stage of development and may not be successfully developed or commercialized.

Some of our current product candidates are in preclinical development and will require substantial further capital expenditures, development, testing, and regulatory approval prior to commercialization. We have limited experience designing clinical trials and have not yet filed or supported a marketing application. We may be unable to design and execute a clinical trial that ultimately supports marketing approval.

The time required to obtain approval from the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. The outcome of studies is also inherently uncertain. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval process and are commercialized. The results of nonclinical studies, interim or top line studies, and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety, purity, and potency traits despite having progressed through nonclinical studies and initial clinical trials. Nonclinical and early clinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies have suffered significant setbacks in advanced clinical trials, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants.

[Table of Contents](#)

Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for, or successfully commercialize any of, our product candidates could result in the failure of our business and a loss of all of our stockholders' investment.

Our product candidates may fail at any stage of preclinical or clinical development, and may also reveal unfavorable product candidate characteristics, including safety concerns or the failure to demonstrate efficacy in initial clinical trials. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. Although we anticipate completing the preclinical development, including toxicology testing and clinical supply manufacturing development, necessary to file an investigational new drug application ("IND") for SER 252 and additional INDs for other product candidates in the future, we may experience numerous unforeseen events before, during, or as a result of clinical trials that could delay or prevent our ability to commence or complete development, commence or complete clinical trials, receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient nonclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- regulators or independent review boards ("IRBs") or Independent Ethics Committees ("IECs") may not authorize us or our investigators to commence or continue a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- Regulators, independent data safety monitoring committees, IRBs or IECs, we, or our data monitoring committee(s) may recommend or require the suspension or termination of clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks, undesirable side effects, or a failure of the product candidate to demonstrate any benefit to subjects, or other unexpected characteristics (alone or in combination with other products) of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- new information may emerge regarding our product candidates or technology platform that result in continued development of some or all of our product candidates being deemed undesirable;
- we may have delays identifying, recruiting, and training suitable clinical investigators or investigators may withdraw from our studies;
- we may experience delays in reaching, or failing to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or contract research organizations ("CROs"). Contractual terms can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- 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 or be lost to follow up at a higher rate than we anticipate for a number of reasons, such as adverse events, an inadequate treatment response, fatigue with the clinical trial process or personal issues;
- patients who enroll in our studies may misrepresent their eligibility or may otherwise not comply with clinical trial protocols, resulting in the need to drop those patients from those studies, increase the needed enrollment size for those studies, or extend the duration of those studies;
- there may be flaws in our study design, which may not become apparent until a study is well advanced;

[Table of Contents](#)

- our contractors may fail to comply with regulatory requirements or clinical trial protocols, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- regulatory authorities or IRBs/IECs may disagree with the design, including endpoints, scope, or implementation of our clinical trials, or regulatory authorities may disagree with our intended indications;
- regulatory authorities may disagree with the formulation for our product candidates, or our product candidate dose or dosing schedule;
- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe, pure, and potent for any indication;
- regulatory authorities may not accept, or we or our clinical trials may not meet the criteria required to submit, clinical data from trials which are conducted outside of their jurisdictions;
- the results of clinical trials may be negative or inconclusive, may not meet the level of statistical significance required for, or may not otherwise be sufficient to support marketing approval, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials, analyses, reports, data, or nonclinical studies, or abandon product development programs;
- our product candidates may have undesirable or unintended side effects, toxicities, or other characteristics that preclude marketing approval or prevent or limit commercial use;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks or otherwise provide an advantage over current standard of care or current or future competitive therapies in development;
- the standard of care for the indications we are investigating may change, which changes could impact the meaningfulness of the resulting study data, or which may necessitate changes to the studies;
- regulatory authorities may disagree with the scope, design, including endpoints, implementation, or our interpretation of data from nonclinical studies or clinical trials;
- regulatory authorities may require us to amend our studies, perform additional or unanticipated clinical trials or nonclinical studies or manufacturing development work to obtain approval or initiate clinical trials, or we may decide to do so or abandon product development programs;
- regulatory authorities may find that we or our third-party manufacturers do not satisfy regulatory requirements and standards for the facilities and operations used in the manufacture of our product candidates;
- the cost of clinical trials of our product candidates may be greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA or other regulatory authorities upon the filing of a marketing application;
- 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 take longer than we anticipate to make a decision on our product candidates; or

[Table of Contents](#)

- changes in, or the enactment of, the approval policies, statutes, or regulations of the applicable regulatory authorities may significantly change in a manner rendering our nonclinical or clinical data insufficient for approval.

Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

A clinical trial may be suspended or terminated by us, our partners, the IRBs of the institutions in which such trials are being conducted, the Data and Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of any of our potential future product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process, and jeopardize our ability to commence product sales and generate revenue, and we may not have the financial resources to continue development of the product candidate that is affected or any of our other product candidates. We may also lose, or be unable to enter into, collaborative arrangements for the affected product candidate and for other product candidates that we are developing. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our potential future product candidates.

Preliminary results from our nonclinical studies and clinical trials that we announce or publish from time to time may change as more patient data becomes available and as the data undergoes audit and verification procedures.

From time to time, we may publish interim, topline, or preliminary results from our nonclinical studies and clinical trials. Preliminary and interim results from our clinical trials are not necessarily predictive of final results and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary, interim, and topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, preliminary, interim, and topline data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the preliminary, interim, or topline data could significantly harm our business prospects.

Further, others, including regulatory agencies, 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 approval or commercialization of the particular product candidate or therapeutic product, if any, and us in general. In addition, the information we choose to publicly disclose regarding a particular nonclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapeutic product, if any, product candidate or our business. If the preliminary, interim, and topline 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.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans, and we may fail to obtain regulatory approval of our product candidates.

The FDA standard for approval of a drug or biologic generally requires two adequate, well-controlled clinical trials, each convincingly demonstrating the product candidate's safety and effectiveness, or one large and robust, well-controlled trial providing substantial evidence that the product candidate is safe and effective for proposed indication. Phase III clinical trials typically involve hundreds of patients, have significant costs and take years to complete. Product candidates studied

[Table of Contents](#)

for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA usually requires a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals.

Our clinical trial results may not support either accelerated or regular approval. The results of nonclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that our product candidates’ risk-benefit ratios for their proposed indications are acceptable;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a new drug application (“NDA”) or biologics license application (“BLA”) or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third-party manufacturer’s facilities with which it contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects.

Failure of our technology would significantly harm our business, results of operations, and prospects.

We may not be successful in our efforts to use and expand our discovery engine to build a pipeline of product candidates.

[Table of Contents](#)

A key element of our strategy is to use and expand our POZ Platform drug delivery technology to build a pipeline of product candidates and progress these product candidates through preclinical and clinical development for the treatment of various diseases. Although our research efforts to date suggest that the POZ Platform technology can deliver payloads including small molecules, proteins, and nucleic acids, this hypothesis may prove incorrect, or we may not be able to identify a product candidate that is safe or effective as a treatment for various diseases. Further, the scientific evidence to support the feasibility of developing viable product candidates based on our platform has not been established.

Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing;
- a product candidate may upon further study demonstrate harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause it to cease operations. Even if we receive FDA approval to market additional product candidates, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

We may seek designations under FDA programs designed to facilitate and potentially expedite product candidate development, such as fast track or breakthrough therapy designation. Our product candidates may not receive any such designations or if they do receive such designations they may not lead to faster development or regulatory review or approval and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek designations under the FDA's expedited programs for serious conditions, such as fast track or breakthrough therapy designation, which are intended to facilitate and expedite the development or regulatory review or approval process for product candidates.

[Table of Contents](#)

The granting of fast track or breakthrough therapy designation to an investigational product is entirely within the FDA's discretion. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of a fast track or breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidate no longer meets the designation conditions, in which case any granted designations may be revoked, or the agency may decide that the time period for review or approval of the product candidate will not be shortened.

If we are unable to obtain approval via the accelerated approval pathway, we may be required to conduct additional nonclinical studies or clinical trials. Even if we receive accelerated approval from the FDA, the FDA may seek to withdraw accelerated approval.

We may seek an accelerated approval development pathway for our product candidates.

If we choose to pursue accelerated approval, we intend to seek feedback from the FDA or will otherwise evaluate our ability to seek and receive such accelerated approval. After our evaluation of the feedback from the FDA or other factors, we may decide not to pursue or submit an NDA for accelerated approval or any other form of expedited development, review, or approval. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type and may require it to have a confirmatory trial to verify the clinical benefit of the product underway and partially or fully enrolled before granting approval. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA.

Even if we receive accelerated approval from the FDA, we will be subject to rigorous post marketing requirements, including the completion of confirmatory post market clinical trials, submission to the FDA of periodic progress reports on confirmatory trials, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post market study with due diligence; a post market study does not confirm the predicted clinical benefit; other evidence shows that the product is not safe or effective under the conditions of use; or if we disseminate promotional materials that are found by the FDA to be false and misleading. Under the Consolidated Appropriations Act for 2023 (the "CAA"), the FDA may use expedited procedures to withdraw any product for which we receive accelerated approval if our confirmatory trials fail to verify the purported clinical benefits.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate that we may choose to develop would delay our commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

If we apply for orphan drug designation from the FDA, there is no guarantee that we will be able to obtain or maintain this designation, receive this designation for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation ("ODD") must be requested before submitting an NDA. In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user fee waivers. After the FDA grants ODD, the generic identity of the drug and our potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has ODD subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not

[Table of Contents](#)

approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our drug candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. We may not be able to initiate or continue conducting clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials. The enrollment of patients depends on many factors, including:

- the number of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for subjects and clinical trial sites;
- the severity of the disease under investigation and the existence of current treatments;
- the perceived risks and benefits of the product candidate, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies;
- the subject eligibility criteria defined in the protocol, as well as our ability to compensate subjects for their time and effort;
- the size and nature of the patient population;
- the proximity and availability of clinical trial sites for prospective subjects;
- the design of the trial, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- subjects' and investigators' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the product candidate;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

[Table of Contents](#)

- patient referral practices of physicians and the effectiveness of publicity created by clinical trials sites regarding the trial;
- the ability to adequately monitor subjects during and after treatment and compensate them for their time and effort;
- the ability of our clinical study sites, CROs, and other applicable third parties to facilitate timely enrollment;
- the ability of clinical trial sites to enroll subjects that meet all inclusion criteria and any patient exclusion due to erroneous enrollment;
- our ability to obtain and maintain subject informed consents; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion of the study or not return for post study follow up, especially subjects in control groups.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because 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 is limited, we may 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. Moreover, because our product candidates represent a departure from more commonly used methods for disease treatment, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in any future clinical trial.

Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Moreover, a significant number of withdrawn subjects would compromise the quality of our data. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, or the inability to complete development of our product candidates, which could cause the value of our company to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent our regulatory approval or commercialization or limit our commercial potential.

As with most new drugs, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects caused by any potential future product candidate could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. We have not yet completed all clinical trial phases for any of our current product candidates, and it is possible that there will be side effects associated with their use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could order it to cease further development of, or deny approval of, a product candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

If one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long term follow up observation period recommended or required for

[Table of Contents](#)

patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approvals of such products;
- regulatory authorities may require the addition of labeling statements, specific warnings or contraindications;
- we may be required to create a risk evaluation and mitigation strategy plan (a “REMS”), which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for health care providers, and/or other elements to assure safe use;
- we may be required to change the way such products are distributed or administered, or change the labeling of the products;
- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post marketing testing and surveillance to monitor the safety and efficacy of the products;
- we may decide to recall such products from the marketplace after they are approved;
- we could be sued and held liable for harm caused to individuals exposed to or taking our products; and
- our reputation may suffer.

In addition, adverse side effects caused by any therapeutics that may be similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

We may form or seek strategic partnerships or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

From time to time, we may form or seek strategic partnerships or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any such relationships may require us to incur non-recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. These relationships also may result in a delay in the development of our product candidates if we become dependent upon the other party and such other party does not prioritize the development of our product candidates relative to our other development activities. Additionally, any collaborations or licensing arrangements would be subject to the same product candidate development and compliance risks and obligations as we would be if we were to develop the product candidate on our own. Should any third party with which we enter into any of these arrangements not comply with the applicable regulatory requirements, we or they may be subject to regulatory enforcement action and we or they may be delayed or prevented from obtaining marketing approval for the applicable product candidate.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangement for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. Any licensed products may also subject us to the risk of regulatory enforcement should the product or business not be compliant with applicable

[Table of Contents](#)

regulatory requirements. We cannot be certain that, following a strategic transaction or licensing arrangement, we will achieve the revenue or specific net income that justifies such a transaction.

We rely on contract manufacturing organizations to manufacture our nonclinical and clinical pharmaceutical supplies and expect to continue to rely on CMOs to produce commercial supplies of any approved product candidate, and our dependence on CMOs could adversely impact our business.

We rely on contract manufacturing organizations (“CMOs”) for the manufacture of nonclinical and clinical supplies for our product candidates and plans to continue to do so for commercial supplies should we receive marketing approval for any of our product candidates. This reliance also results in our reduced control over the manufacture of our product candidates and the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure, which may adversely affect our future business prospects. Nevertheless, as the developer of the product candidates and sponsor of clinical trials involving such product candidates, we continue to have regulatory obligations to maintain oversight of the CMOs to ensure compliance with, among other things, contractual obligations, specifications, and the current good manufacturing regulations enforced by the FDA (“cGMP”).

In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money, and effort in the areas of design and development, testing, production, record keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. Although our agreements with our CMOs require them to perform according to certain cGMP such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If our CMOs do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to support the commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to produce, or may be delayed in producing sufficient product to meet our supply requirements. Any delays in obtaining adequate supplies on adequate terms with respect to our product candidates and components, due to manufacturing issues, global trade policies, or for other reasons, may delay the development, approval, or commercialization of our product candidates.

We may not succeed in our efforts to establish manufacturing relationships on commercially reasonable terms. Our product candidates may compete with other products and product candidates for access to manufacturing facilities, of which there are a limited number that operate under cGMP conditions and that are both capable of manufacturing our product candidates and willing to do so. Even if it does establish such collaborations or arrangements, our CMOs may breach, terminate, or not renew these agreements. These facilities may also be affected by a global pandemic, natural disasters such as floods, fires, explosions or such facilities could face manufacturing issues, such as contamination or adverse regulatory findings following a regulatory inspection. Further, our CMOs may be temporarily unable to manufacture our product candidates due to government restrictions, requirements, or limitations. If our CMOs cease to manufacture our product candidates for any reason, we would experience delays in obtaining sufficient quantities of our product for us to meet commercial demand if we receive marketing approval or in advancing our development programs while we identify and qualify replacement suppliers. We could also incur added costs and delays in identifying and qualifying any such replacements and transferring any necessary technology and processes. The terms of a new arrangement may also be less favorable than any prior arrangements if we are able to negotiate a new arrangement at all. The addition of a new or alternative CMO may also require FDA approval and may have a material adverse effect on our business.

We or our CMOs may also encounter shortages in the raw materials or substances necessary to produce our product candidates in the quantities and at the quality needed for our nonclinical studies and clinical trials or, if any of our product candidates are approved for commercialization, to produce our products on a commercial scale, meet an increase in demand, or compete effectively. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by our competitors or others. Our or our third-party manufacturers’ failure to obtain the raw materials or substances necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

Moreover, any problems or delays we experience in preparing for commercial scale manufacturing of a product candidate or component, including manufacturing validation, may result in a delay in a future marketing approval, if any, or commercial launch of any of our product candidates, should they receive regulatory approval, or may impair our ability to manufacture commercial quantities or manufacture such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of our product candidates, if approved, and could adversely affect our

[Table of Contents](#)

business. Furthermore, if the future manufacturers of the commercial supplies of our products, if approved, fail to deliver the required commercial quantities of our product candidates on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we could lose potential revenues. The manufacture of drugs requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of drugs often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. If our manufacturers were to encounter any of these difficulties and were unable to perform as agreed, our ability to provide our product candidates for use in nonclinical studies or our current and planned clinical trials, or, if any of our product candidates are approved, our ability to produce our product for commercial use, could be jeopardized.

In addition, all manufacturers of our product candidates used in clinical trials and of our products for commercial supply, should any of our product candidates receive regulatory approval, must comply with cGMP regulations promulgated by the FDA and equivalent foreign regulatory authorities that are applicable to both finished products and their active components used both for clinical and commercial supply. Regulatory authorities enforce these requirements through facility inspections. CMO facilities must be satisfactory to the FDA and equivalent foreign regulatory authorities as determined by inspections that will be conducted after we submit our marketing applications to the appropriate agencies and prior to product approval and commercialization. Our CMOs will also be subject to continuing, periodic regulatory authority inspections should our product candidates receive marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing, and control documentation to the FDA and equivalent foreign regulatory authorities in support of a marketing application on a timely basis.

The cGMP include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with our specifications, cGMP or with other applicable regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our CMOs cannot successfully manufacture material that conforms to our specifications and the applicable regulatory requirements, they may not be able to secure or maintain regulatory acceptance of their manufacturing facilities for the purpose of producing our product candidates.

Deviations from manufacturing requirements may also require reporting and remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, if any of our product candidates receives regulatory approval, or the temporary or permanent closure of a facility. Any such remedial measure could materially harm our business. Any delay in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to nonclinical studies and clinical trials, or potential product approvals or commercialization. Any such delay may also require that we conduct additional studies.

While we are ultimately responsible for the manufacture and regulatory compliance of our products and product candidates, we have little control over our manufacturers' compliance with these regulations and standards other than through our contractual arrangements. If the FDA or a comparable foreign regulatory authority does not find these facilities satisfactory for the manufacture of our products, if approved, or product candidates or if such authorities find such facilities to be noncompliant in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain and maintain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA or other relevant comparable regulatory authority approval for the use of any new manufacturers for commercial supply.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulatory requirements may result in regulatory enforcement actions against our manufacturers or ourselves, including fines and civil and criminal penalties, including suspension of, or restrictions on, production, injunctions, delay, withdrawal or denial of product approval or supplements to approved products, clinical holds or termination of clinical studies, warning or untitled letters, regulatory authority communications warning the public about safety issues with a product, refusal to permit the import or export of a product, product seizure, detention, or recall, operating restrictions, civil penalties, criminal prosecution, corporate integrity agreements, or consent decrees and equivalent foreign sanctions. Depending on the severity of any potential regulatory

[Table of Contents](#)

action, supplies of our product candidates or products, if approved, could be interrupted or limited, which could have a material adverse effect on our business.

We rely on third parties to conduct some of our nonclinical studies and all of our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for, or commercialize, our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our clinical trials ourselves and do not currently plan to independently conduct clinical trials. We use third parties, such as CROs, to conduct, supervise, and monitor the clinical trials and will rely upon such CROs, as well as medical institutions, investigators, and consultants, to conduct any future clinical trials that we may conduct in accordance with our protocols and applicable laws and regulations. In addition, we occasionally use third parties to conduct our nonclinical studies. Our CROs, investigators and other service providers play a significant role in the conduct of clinical trials and the subsequent collection and analysis of data from such trials.

Our service providers are not our employees and, except for remedies available to us under our agreements with such third parties, as a result we will have less control over the timing, quality and other aspects of such nonclinical studies and clinical trials than we would have if we were to conduct them on our own. If these third parties do not successfully carry out their contractual duties to us, meet our expected timelines or conduct our nonclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or applicable regulatory requirements or for other reasons, our trials may need to be repeated, extended, delayed, or terminated. Further, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we may fail or be delayed in our efforts to successfully commercialize our product candidates, if approved. Such failures may also subject us or our third-party service providers to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of service providers in the future, our business may be materially and adversely affected. Our third-party service providers may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position.

Agreements with third parties conducting or otherwise assisting with our nonclinical studies or clinical trials might terminate for a variety of reasons, including a failure to perform by such parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with suitable alternative providers or do so on commercially reasonable terms. Switching or adding third parties involves additional cost and requires management time and focus. There is also a natural transition period when a new third party commences work. As a result, if we need to enter into alternative arrangements, it could delay our product development activities and adversely affect our business. Although we carefully manage our relationships with our third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

Our reliance on third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our oversight and regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for that trial. We must also ensure that our nonclinical studies are conducted in accordance with good laboratory practice (“GLP”) requirements, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with established good clinical practice (“GCP”) standards 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, integrity, and confidentiality of trial participants are protected. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP conditions. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical and nonclinical investigators, manufacturers, and trial sites. If we or any of our third-party service providers fail to comply with applicable regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies, which may significantly delay our clinical development plans and the regulatory approval process. We cannot assure you that upon inspection by a

[Table of Contents](#)

given regulatory authority, such regulatory authority will determine that we, our third-party service providers, or clinical trial sites are in substantial compliance with the applicable regulatory requirements.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest. We are also required to register certain clinical trials and post the results of certain completed clinical trials on a government sponsored database, clinicaltrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

We rely on other third parties to store and distribute our product candidates for nonclinical studies and clinical trials that we conduct.

We also rely on other third parties to store and distribute our product candidates for the nonclinical studies and clinical trials that we are conducting or plan to conduct. Any performance failure, or failure to comply with applicable regulations, on the part of our distributors could delay development, the regulatory approval process, or potential commercialization of our product candidates, producing additional losses and depriving us of potential product revenue.

We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if the use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. We will face an even greater risk of product liability if we receive marketing approval for and commercialize any of our product candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, health care providers or others using, administering, or selling our products.

Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources, or destroy the prospects for commercialization of the product which is the subject of any such claim. For instance, product liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- incurred costs and time of related litigation;
- substantial monetary awards to patients or other claimants, and loss of revenue;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- a decrease in the value of Serina;
- initiation of investigations, and enforcement actions by regulators; and/or

[Table of Contents](#)

- product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit development or commercialization of our products or product candidates. Although we maintain product liability and clinical trial insurance coverage, it may be inadequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical development of our product candidates and if we successfully commercialize any medicine. 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.

Risks Related to Our Business, Industry, and Future Commercialization

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, health care payors and the medical community, the revenues that we generate from their sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, health care payors and the medical community. Market acceptance of our products by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control, including:

- the efficacy of our products and the prevalence and severity of any adverse events;
- any potential advantages or disadvantages when compared to alternative treatments;
- interactions of our products with other medicines patients are taking and any restrictions on the use of our products together with other medications;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for such product candidates, which could reduce the marketing impact of any claims that we could make following approval, if obtained;
- the safety, efficacy, and other potential advantages over alternative treatments, such as relative convenience and ease of administration of such products, and the availability of alternative treatments already used or that may later be approved;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of formulary coverage and adequate coverage or reimbursement by third parties, such as insurance companies and other health care payors, and by U.S. and international government health care programs, including Medicaid and Medicare;
- the price concessions required by third-party payors and government health care programs to obtain coverage and payment;
- the extent and strength of our marketing and distribution of such products;

[Table of Contents](#)

- distribution and use restrictions imposed by the FDA and equivalent foreign regulatory authorities with respect to such products or to which we agree, for instance, as part of a REMS or voluntary risk management plan;
- the timing of market introduction of such products, as well as competitive products;
- our ability to offer such products for sale at competitive prices;
- our ability to offer programs to facilitate market acceptance and insurance coverage from public and private insurance companies, provide patient assistance, and transition patient coverage;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the approval of other new products, including biosimilar products that may be priced at a substantially lower price than we expect to offer our product candidates for, if approved;
- adverse publicity about the product or favorable publicity about competitive products;
- the success of any efforts to educate the medical community and third-party payors regarding our products, which efforts may require significant resources and may not be successful; and
- potential product liability claims.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, health care payors and patients, we may not generate sufficient revenue from these products and may not become or remain profitable.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our current and future product candidates if and when they are approved.

There are risks involved with both establishing and managing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

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

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians to discuss our products;

[Table of Contents](#)

- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors, and to secure adequate coverage;
- reduced realization on government sales from mandatory discounts, rebates and fees, and from price concessions to private health plans and pharmacy benefit managers necessitated by competition for access to managed formularies;
- the clinical indications for which the products are approved and the claims that we may make for the products, as well as any limitations on use or warnings;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions, and any liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- restricted or closed distribution channels that make it difficult to distribute our products to different segments of the patient population;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenues, or the profitability of these product revenues to us may be lower than if we were to market and sell any product that we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our products or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any products we may develop.

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new drugs is highly competitive. Moreover, the CNS and drug delivery fields are characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will likely face competition with respect to any product candidates that we may seek to develop or commercialize in the future from numerous pharmaceutical and biotechnology organizations, as well as from academic institutions, government agencies and other public and private research organizations for our current and future product candidates. Our commercial success will be reduced or eliminated if our competitors develop products that are safer, more effective, or less costly than ours.

A number of well-resourced pharmaceutical and biotechnology companies are developing products anticipated to be in competition with our product candidates and our drug delivery platform technology. These products and technologies, as well as marketing campaigns by competitors and clinical trial results with competitive products, could significantly diminish our ability to market and sell our future products.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical 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

[Table of Contents](#)

number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and 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 product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than the product candidates we may develop or that would render any of our product candidates obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Our commercial opportunity may also be reduced or limited if we or our partners are unable to scale up the manufacture of our product candidates to meet clinical or commercial requirements. The compositions we seek to develop may exhibit poor pharmaceutical properties, and formulation, purification and stable storage could be challenging.

In addition, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of competitive products could limit the demand and the price we are able to charge for our products. Further, intellectual property protection for our POZ platform technology and our product candidates is dynamic and rapidly evolving. The scope of intellectual property protection for our POZ platform may be limited, and our commercial opportunity may be reduced or limited if our competitors are able to acquire or develop the same or similar technologies.

Corporate and academic collaborators may take actions to delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on our entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties and we may not be successful in establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and may not be within our power to influence. Any collaborators may not perform their obligations to our satisfaction, or at all, we may not derive any revenue or profits from such collaborations, and any collaborators may ultimately compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials and our business. If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, reimbursement practices, or health care reform initiatives, which would harm our business.

The regulations that govern pricing and reimbursement for new medicines vary widely from country to country, and current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Outside the United States, some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates we may develop, even if any such product candidates obtain marketing approval.

[Table of Contents](#)

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government authorities or health care programs, private health plans, and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary and/or cost effective, and the amount reimbursed for any products may be insufficient to allow it to sell our products on a competitive basis. At this time, we are unable to determine their cost effectiveness or the likely level or method of reimbursement for our product candidates. Government authorities and third-party payors, such as private health plans, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. health care 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 challenging the prices charged for medical products and requiring that biopharmaceutical companies provide them with predetermined discounts from list prices. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the products are used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product by increasing the administrative burden associated with our prescription or creating coverage uncertainties for prescribers and patients. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain therapeutic products that are not usually self-administered (such as most injectable drugs and biologics) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician's services;
- they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

There may be significant delays in obtaining reimbursement for newly approved product candidates, and coverage may be more limited than the purposes for which the product candidate is approved by the FDA or other regulatory authorities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to pay all or part of the costs associated with their prescription medications. Patients are unlikely to use our products unless coverage is provided, and payment is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate payment is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Moreover, eligibility for reimbursement does not imply that any product candidate 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 product candidates, 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 product candidate and reimbursement in the clinical setting in which it is used may be based on reimbursement levels already set for lower cost therapies or medicines and may be incorporated into existing payments for other services. Net prices for product candidates may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for any approved product candidates we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We carry insurance for most categories of risk that our business may encounter; however, we may not have adequate levels of coverage. We currently maintain general liability, property, workers' compensation, products liability and directors' and officers' insurance, along with an umbrella policy. We may not be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Risks Related to Our Intellectual Property

Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to protect and/or enforce our intellectual property.

Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully enforcing our patents against third-party infringers and/or defending these patents against third-party challenges. If we (or our licensees should such licensees be granted the right to prosecute or enforce certain patents within our portfolio) fails to appropriately prosecute or is unable to obtain and maintain patent protection for our product candidates (or aspects thereof), our ability to develop, license and/or commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using, selling or importing competing products. This failure or inability to properly or adequately protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining, enforcing and defending patents. These risks and uncertainties include the following:

- patent applications may not result in any patent being issued;
- patents that may be issued may not include claims that cover a broad enough scope to prevent design around solutions by competitors;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide adequate barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing, or eliminating any advantage of the patent;
- our competitors, many of which have substantially greater resources than us or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products; and

[Table of Contents](#)

- we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and/or unsuccessful.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and assignment agreements with employees, consultants, and advisors, there exists the potential that third parties may still somehow obtain this information or arrive at the same or similar information independently, which would reduce or eliminate our competitive advantage. Moreover, we may become subject to claims that we directly or indirectly (through our consultants, advisors, or independent contractors that we may engage to assist us in developing our product candidates) have wrongfully or inadvertently disclosed, acquired or used trade secrets or other proprietary information of third parties.

We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable, or limited or narrowed in scope such that we may no longer be used to adequately prevent the manufacture, sale or import of competitive product. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office (the “USPTO”), may place pending applications at risk of non-issuance or limitations in scope. Further, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes review, post grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope, or validity of our patents. Additionally, because of the substantial amount of discovery typically required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information or trade secrets could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the value of the Company. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh Dole Act of 1980. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh Dole Act may similarly apply. Any exercise by the government of certain of our rights could harm our competitive position, business, financial condition, results of operations and prospects.

If we or our partners are sued for infringing on the intellectual property rights of third parties, it could be costly and time consuming, and an unfavorable outcome in any such litigation could have a material adverse effect on our business.

Our success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing on the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, now unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may be alleged to infringe upon. Similarly, there may be issued patents relevant to our product candidates of which it is not aware.

In addition, third parties may sue us alleging that we infringe, or have infringed, on their patents. Even if we are successful in defending any claims of infringement, the defense of such claims may be costly and present a time consuming distraction. In the event of a successful claim of infringement against us, we may be required to:

[Table of Contents](#)

- pay substantial damages and/or ongoing royalty payments;
- stop using some or all of our technologies and methods;
- stop certain research and development efforts;
- develop non infringing products or methods (i.e., develop or design around); and/or
- obtain one or more licenses from third parties for an upfront lump sum, an ongoing royalty, or a combination thereof.

If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in the development, manufacture, and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we allegedly infringe on third party rights, could be costly, time consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research endeavors that are similar to those which they were involved in at their former place of employment, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of such former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs, be a distraction to management and ultimately have a material adverse effect on us, even if we are successful in defending such claims.

The biotechnology and pharmaceutical industries have experienced substantial litigation and other proceedings concerning intellectual property rights, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which could be uncertain and may prevent, delay, or otherwise interfere with our product discovery and development efforts. Our commercial success depends upon our ability and the ability of our collaborators and licensors to develop, manufacture, market, and sell our products. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to, and may in the future become party to, or threatened with, adversarial proceedings or litigation concerning intellectual property rights with respect to our POZ platform and any product candidates we may develop, including interference proceedings, post grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office (the "EPO"). Numerous United States and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and infringement claims may be asserted against us or our partners based on existing patents or patents that may be granted in the future, regardless of their merit.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our POZ platform and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. Moreover, as with many technology-based products, there may be third-party patent applications that, if issued, may include the claims that could be or are construed to cover components of our POZ platform and product candidates. There may also be third party patents of which we are currently unaware with claims to our technologies, compositions, methods of manufacture or methods of use.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot successfully defend against infringement claims or obtain a license on commercially reasonable terms to relevant third party patents that cover our product candidates. Even if we have a strong defense and/or believe that third-party intellectual property claims are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability, and/or priority. A court of competent jurisdiction could hold that these third party patents are valid and enforceable and have been infringed upon, which could materially and adversely affect our ability to commercialize our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As

[Table of Contents](#)

this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the asserted claims of any such U.S. patent. If we are found to be infringing on a third party's intellectual property rights, and we are unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to pay damages and/or an ongoing royalty or obtain a license from such third party to continue developing, manufacturing, and marketing our product candidates and our technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to it, and it could require us to pay substantial licensing fees and/or make ongoing royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our POZ platform or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. While less likely given the high bar required for injunction, we also could be temporarily or permanently forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed on a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

The defense of third-party claims of alleged infringement, misappropriation, or violation of intellectual property rights often involves substantial litigation expense and could also be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications are due to be paid to the USPTO and foreign patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In the case of any in-licensed patent rights, we generally rely on our licensors to pay these fees due to U.S. and non U.S. patent agencies. For patent rights we own, we rely on our outside patent counsel and/or annuity services in the United States and foreign countries to monitor these deadlines and to pay these fees when so instructed by us.

The USPTO and foreign patent agencies require compliance with procedural, documentary, fee payment, and other similar provisions, such as the requirement to disclose known prior art, during the patent application process. In the case of any in-licensed patent rights, we generally depend on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property, and for our owned patent applications, we engage counsel and other professionals to help us comply with these requirements. While certain inadvertent lapses can be cured by payment of a late fee, by petition, or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in a partial or complete loss of patent rights in the relevant jurisdiction. In the unlikely event that a non-compliance event were to occur, our competitors might be able to enter the market with similar or identical products or technology given our partial or complete loss of patent rights, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension for our drug candidates, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA regulatory approval of our drug candidates, one or more patents issued from U.S. patent applications that we file or those of our future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A maximum of one patent may be extended per FDA-approved drug as compensation for the patent term lost

[Table of Contents](#)

during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our drug candidates.

Despite the possibility of an extension, we may not be granted an extension for which it applies in the United States or any other jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than we request.

If we are unable to obtain patent term extension or restoration, or the foreign equivalent, or the term of any such extension is less than we request, our competitors or other third parties may obtain approval of competing drugs following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third parties may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case. Any of the foregoing could materially harm our business, financial condition, results of operations and prospects.

Changes in patent law in the United States and in non U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our technologies and product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and are therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents. For example, in March 2013, under the America Invents Act, the United States transitioned from a “first to invent” to a “first to file” patent system. Under a “first to file” system, assuming that other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on an invention regardless of whether another inventor had made the invention earlier. A third party that filed a patent application in the USPTO after March 2013, but before Serina filed could therefore be awarded a patent covering an invention of ours even if Serina had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that it or any licensors were the first to either file any patent application related to our technologies or product candidates or invent any of the inventions claimed in our or our licensor’s patents or patent applications. The America Invents Act also includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted, allowing third-party submission of prior art, and establishing a new post grant review system, including post grant review, inter partes review, and derivation proceedings. Because of the lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts 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 district court action. Accordingly, a third party may attempt to use USPTO proceedings to invalidate our patent claims even though the claim would not have been invalidated if first challenged by the third party in a district court action.

In addition, U.S. Supreme Court rulings over the past decade have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of issued patents. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce and/or defend our existing patents and patents that we might obtain in the future.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from the earliest non provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and also depends upon many factors, including

[Table of Contents](#)

the type of patent, the scope of coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent, and whether a portion of the patent term has been terminally disclaimed based on other patents. Various extensions including patent term extension and patent term adjustment may be available, but the lives of such extensions, and the protections they afford, are limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and/or licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours for an adequate time period.

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

In addition to seeking patents for our technologies and product candidates, we also rely on trade secret protection, as well as confidentiality agreements, non-disclosure agreements and assignment agreements with our employees, consultants and third parties, to protect our know-how and other confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party's relationship with us are to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements also provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third-party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not be able to obtain adequate remedies for any breaches of such agreements. Ultimately, enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time consuming, and the outcome is unpredictable.

In addition to contractual measures, we protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect despite these precautions. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, our trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. Even if we are successful, these types of lawsuits may consume, in addition to substantial costs, significant amounts of our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that our employees, consultants, or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we employ measures to ensure that our employees, consultants, and

[Table of Contents](#)

advisors 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 these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We may then be directly or indirectly involved in litigation proceedings to defend against these claims. If we fail in defending against any such claims, in addition to potentially paying monetary damages, we may lose valuable intellectual property rights and/or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Ultimately, any such litigation could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately engage in such litigation. For example, some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. However, our 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 benefit from to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties 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 allegations of 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 diversions of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, any proprietary name we propose to use with any product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit it to maintain our competitive advantage. For example:

- any of our current and future product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make immunotherapies that are similar to any of our current and future product candidates or utilize lymph node targeting technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our licensors or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future, potentially resulting in the invalidation of such patents or refusal of such applications;

[Table of Contents](#)

- we, or our licensors or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our licensors or current or future collaborators, may fail to meet our obligations to the U.S. government regarding any in licensed patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights;
- it is possible that our pending, owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, or parts of our owned or in-licensed patents;
- it is possible that there are unpublished patent applications that may later issue with claims covering our product candidates or technology similar to ours;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or result in a change in ownership;
- issued patents to which we hold rights may be held invalid, unenforceable, or narrowed in scope, including as a result of legal challenges by our competitors;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or narrowly cover our product candidates in such a way that competitors may be able to design around to avoid infringement allegations;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of our licensors or current or future collaborators to the same extent as the laws of the United States;
- the inventors of our owned or in licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to it or the patents or patent applications on which they are named as inventors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- any product candidates we develop may be covered by third-party patents or other exclusive rights;
- the patents of others may prohibit or otherwise harm our business; or

[Table of Contents](#)

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently commercialize the technology and/or file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Regulatory and Compliance Matters

The FDA regulatory approval process is lengthy, time consuming, and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, adverse event reporting, record keeping, advertising, promotion, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any drug product in the United States until we receive approval from the FDA. We have not previously submitted an NDA to the FDA, or similar approval filings to comparable foreign authorities. An NDA must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe, pure, potent, and effective for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre license inspection. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping, conduct of post marketing studies, and submission of safety, efficacy, and other post market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities must comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing applications, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long term patient follow up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that it conducts post approval.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

[Table of Contents](#)

Failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. 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 or other enforcement related letters or clinical holds on post approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Additional regulatory burdens and other risks and uncertainties in foreign markets may limit our growth.

Our future growth may depend, in part, on our ability to develop and commercialize product candidates in foreign markets for which we may rely on strategic partnerships with third parties. We will not be permitted to market or promote any product candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval. To obtain separate regulatory approval in foreign countries, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing, and distribution of a product candidate, and it cannot predict success in these jurisdictions. If we obtain approval of any of our potential future product candidates and ultimately commercialize any such product candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

In addition, obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

[Table of Contents](#)

Health care and other reform legislation may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U.S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates or any potential future product candidates of ours, restrict or regulate post approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post marketing testing and other requirements. Congress also must reauthorize the FDA's user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. Congress most recently reauthorized the user fee programs in September 2022 without any substantive policy changes.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the Patient Protection and Affordable Care Act of 2010, as amended (the "ACA"), which substantially changed the way health care is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There remain judicial and Congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the law's constitutionality. Further legislative and regulatory changes under the ACA remain possible. It is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing, or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and was extended by the CAA. The CAA will remain in effect through 2032 unless additional Congressional action is taken.

In addition, the Drug Supply Chain Security Act enacted in 2013 (the "DSCSA") imposed obligations on manufacturers of pharmaceutical products related to product tracking and tracing, and in February 2022, the FDA released proposed regulations to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA. As another example, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law that includes a piece of bipartisan legislation called the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel such brand manufacturer to furnish the necessary samples on "commercially reasonable, market based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and the potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post approval requirements and restrict sales and promotional activities for pharmaceutical products. We are unsure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or whether such changes will have any impact on our business.

[Table of Contents](#)

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, state legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

At the federal level, the Department of Health and Human Services (the "HHS") has solicited feedback on various measures intended to lower drug prices and reduce the out of pocket costs of drugs and has implemented others under our existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

In August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 (the "IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease.

More recently, 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.

Many European Economic Area ("EEA") countries periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in EEA countries will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EEA countries, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA countries, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA countries. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EEA countries.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EEA countries in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EEA level for joint clinical assessments in these areas. This Regulation foresees a three-year transitional period and will permit EEA countries to use common HTA tools, methodologies, and procedures across the EEA, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EEA countries will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical)

[Table of Contents](#)

aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EEA countries for drug candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for, those products in the EEA could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the EEA may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for drug candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EEA and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, supranational or national level, or how any future legislation or regulation may affect us, any of which may have a materially adverse effect on our business, financial condition, results of operations and prospects.

Any additional federal or state health care reform measures could limit the amounts that third-party payors will pay for future health care products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants, and commercial partners, and our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA or other regulatory authorities, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing, and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act of 1977 (the “FCPA”) prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

[Table of Contents](#)

Similarly, the U.K. Bribery Act 2010 has extra territorial effect for companies and individuals having a connection with the United Kingdom. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our business outside of the United States, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violations of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. A conviction under the FCPA can result in long term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices could have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Related to Employee and Operations Matters, Managing Growth and Information Technology

A pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The extent to which an outbreak impacts our operations or those of our collaborators will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the virus and the actions to contain it or treat our impact, among others.

The spread of any outbreak globally could adversely impact any preclinical or clinical trial operations in the United States and Europe, including our ability to recruit and retain patients and principal investigators and site staff who, as health care providers, may have heightened exposure to an infectious disease if an outbreak occurs in their geography. For example, similar to other biotechnology companies, we have experienced, and may in the future experience, delays in initiating IND enabling studies, delays in manufacturing, protocol deviations, enrolling patients in clinical trials and dosing patients in clinical trials, as well as in activating trial sites. An outbreak may also result in the need to suspend enrollment in clinical studies, subject withdrawals, postponement of planned clinical or nonclinical studies, redirection of site resources from studies, study modification, suspension, or termination, the introduction of remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes requiring state licensing, study deviations or noncompliance, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, IRBs, and the FDA. The foregoing may also impact the integrity of our study data. The effects of an outbreak may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects. A pandemic could further impact our ability to interact with the FDA or other regulatory authorities and may result in delays in the conduct of inspections or review of pending applications or submissions. For example, the FDA may delay preapproval inspections. Although the FDA lifted restrictions relating to COVID-19 and affecting our inspection and other compliance operations in July 2022, the agency currently faces a significant backlog on compliance monitoring and enforcement activities for both domestic and foreign manufacturers, which may affect the scheduling of necessary preapproval inspections of manufacturing facilities for drug and biological product candidates.

An outbreak may additionally result in changes in laws and regulations. Any future changes in law may require that we change our internal processes and procedures to ensure continued compliance.

Even after an outbreak or pandemic subsides, we may continue to experience an adverse impact to our business as a result of our global economic impact, including from increased inflation and the prospect that policy responses to inflation could delay economic recovery or lead to another recession.

[Table of Contents](#)

Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business, financial condition, results of operation or prospects. Further, uncertainty around these and related issues could continue to adversely impact the economies of the United States and other countries, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

Our future success depends on our ability to recruit and retain our executive team and key scientists and to attract, retain, and motivate qualified personnel.

We are highly dependent on the principal members of our management and scientific teams. These principal members are employed “at will,” meaning we or they may terminate the employment relationship at any time. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, business development, general and administrative and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. In addition, inflation has had, and we expect that it will continue to have, an impact on the costs that we incur to attract and retain qualified personnel and may make it more difficult for us to attract and retain such personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants, or advisors, may impede the progress of our research, development, and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Over time we will need to hire additional qualified personnel with expertise in drug development, product registration, clinical, preclinical, and nonclinical research, quality compliance, government regulation, formulation and manufacturing, financial matters and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense, and our search for such personnel may not be successful. Attracting and retaining qualified personnel will be critical to our success.

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

As of December 31, 2025, we had 16 full time employees and, in connection with the growth and advancement of our pipeline, we expect to increase the number of our employees and the scope of our operations, particularly in the areas of product development, business development, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources, and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced, and we may not be able to implement our business strategy. Our future

[Table of Contents](#)

financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage the future development and expansion of our company.

Our internal computer systems, or those of our vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent it from accessing critical information, potentially exposing it to liability or otherwise adversely affecting our business.

Our internal computer systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to damage, interruption or data theft from computer viruses, computer hackers, malicious code, employee theft or misuse, ransomware, social engineering (including phishing attacks), denial of service attacks, sophisticated nation state and nation state supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cybersecurity incidents, which may not be immediately or ever detected, are increasing in frequency and evolving in nature. Additionally, due to geopolitical tensions related to Russia's invasion of Ukraine, the risk of cyber-attacks may be elevated.

While we seek to protect our information technology systems from system failure, accident, and security breach, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation, and potential notification of the breach to counterparties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. In addition, in response to the ongoing COVID-19 pandemic, some of our workforce began to work remotely. This has continued and is now considered normal business. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruption.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory actions or investigations, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects. While we maintain cyber liability insurance (covering security and privacy matters), such insurance may not be adequate to cover any losses experienced as a result of a cybersecurity incident.

If we experience material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

Our management is responsible for establishing and maintaining internal control over financial reporting, disclosure controls, and compliance with the other requirements of the Sarbanes-Oxley Act and the rules promulgated by the SEC thereunder. As a result of being a public company, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis. We may identify material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate such material weaknesses, we may not be able to report our financial results accurately or prevent fraud.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations.

[Table of Contents](#)

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets, and beginning in 2020 the COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets. See “Risks Related to Employee and Operations Matters, Managing Growth and Information Technology.” A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

U.S. federal income tax reform could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (the “IRS”) and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, President Trump signed into law the CARES Act which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of NOLs, interest deductibility limitations and payroll tax matters. Additionally, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017 (the “TCJA”), which significantly reformed the Code. The TCJA included significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. Under the TCJA, in general, NOLs generated in taxable years beginning after December 31, 2017 may offset no more than 80 percent of such year’s taxable income and there is no ability for such NOLs to be carried back to a prior taxable year. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80 percent of current year taxable income for taxable years beginning before January 1, 2021. As a result of such limitation, we may be required to pay federal income tax in some future year notwithstanding that it had a net loss for all years in the aggregate. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

For the tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 (“TCJA”) eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and 15 years for research activities performed outside the United States pursuant to IRC Section 174. On July 4, 2025, the U.S. Congress enacted the One Big Beautiful Bill Act, which includes provisions that allow for the immediate expensing of domestic U.S. research and development expenses, a general requirement to reduce the deduction for research and development expense by any research credit taken, and other changes to the U.S. taxation of profits derived from foreign operations. We have no assurance as to whether, when and how these provisions may be subject to further amendment or repeal. Such changes, among others, may adversely affect our effective tax rate, results of operation, and general business condition.

We face risks associated with increased political uncertainty.

Military conflict among the United States, Israel and Iran, the invasion of Ukraine by Russia and the conflict among Israel, Hamas and Hezbollah has increased global political uncertainty in Europe and has strained the relations of a significant number of governments, including the United States. Any retaliatory actions taken in response to these conflicts, and the impact on regional or global economies, is unknown but could have a material adverse effect on our business, financial condition and results of our operations.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has made statements and taken actions in recent years that have led to certain changes and may lead to additional changes to U.S. and international trade policies, including imposing tariffs on a variety of countries and products. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange, and other economic activities between major international economies, resulting in a

[Table of Contents](#)

material adverse effect on global economic conditions and the stability of global financial markets. There is substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified, or suspended, or the effect that any such actions would have on us or our industry. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the use of testing facilities in China that we use, including pursuant to our testing arrangements with WuXi AppTec (HongKong) Limited. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if U.S. trade policy results in retaliatory trade actions, such changes could have an adverse effect on our business, financial condition and results of operations.

Risks Related to the Company

We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

We will require substantial additional funds to support our continued research and development activities, including the anticipated costs of nonclinical studies and clinical trials, regulatory approvals, and potential commercialization. Our future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit our ability to achieve our business objectives. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholder's ownership interest in us will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

The market price of our common stock is expected to be volatile.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure by us to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;

[Table of Contents](#)

- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- failure to maintain compliance with the listing requirements of the NYSE American;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

[Table of Contents](#)

Additionally, a decrease in the stock price of our common stock may cause our common stock to no longer satisfy the continued listing standards of the NYSE American. If we are not able to maintain the requirements for listing on the NYSE American, it could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

We will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.

We will incur significant legal, accounting and other expenses that Serina did not incur as a private company, including costs associated with public company reporting requirements. We will also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as the NYSE American rules. These laws, rules and regulations are expected to increase Serina's legal and financial compliance costs and to make some activities more time consuming and costly. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Board or as our executive officers, which may adversely affect investor confidence in us and could cause our business or stock price to suffer.

If we do not continue to satisfy the NYSE American continued listing requirements, our Common Stock could be delisted from NYSE American

The listing of our Common Stock on the NYSE American is contingent on our compliance with the NYSE American's conditions for continued listing. Other than as set forth in the following two paragraphs, while we are presently in compliance with all such conditions, it is possible that we will fail to meet one or more of these conditions in the future.

On January 9, 2026, we were notified by the NYSE American that due to our disclosure in our Quarterly Report on Form 10-Q filed for the fiscal period ended September 30, 2025, which reported stockholders' equity of approximately \$1.6 million, we no longer met the requirement that we must have no less than \$4 million or more in stockholders' equity pursuant to the listing standard set forth under Section 1003(a)(ii) of the NYSE American Company Guide (the "Listing Standards") because we had reported losses from continuing operations and/or net losses in three of our last four most recent fiscal years ended December 31, 2024.

Under the applicable rules of the NYSE American, the Company submitted a compliance plan on February 8, 2026 that demonstrated how it intends to regain compliance with the Listing Standards within 18 months of the receipt of the notice, or July 9, 2027.

If we were to fail to meet a NYSE American listing requirement, we may be subject to delisting by the NYSE American. In the event our Common Stock is no longer listed for trading on the NYSE American, our trading volume and share price may decrease, and we may experience further difficulties in raising capital which could materially affect our operations and financial results. Further, delisting from the NYSE American could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers, and employees, and could also trigger various defaults under our lending agreements and other outstanding agreements. Finally, delisting could make it harder for us to raise capital and sell securities.

Anti-takeover provisions in our governance documents and under Delaware law could make an acquisition of Serina more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in the Amended and Restated Certificate of Incorporation and the Amended and Restated Bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

[Table of Contents](#)

The Amended and Restated Certificate of Incorporation will provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

The Amended and Restated Certificate of Incorporation and the Amended and Restated Bylaws provide, among other things, that that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, the Amended and Restated Certificate of Incorporation or the Amended and Restated Bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. The Amended and Restated Certificate of Incorporation and the Amended and Restated Bylaws will also provide the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against the Company or any of our directors, officers, employees, or agents and arising under the Securities Act. Nothing in the Amended and Restated Certificate of Incorporation or the Amended and Restated Bylaws will preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We do not anticipate paying any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain, if any, for the foreseeable future.

An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

An active trading market for the shares of our common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale discussed in this annual report lapse, the trading price of our common stock could decline. We are not able to predict the effect that sales may have on the prevailing market price of our common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about it and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

[Table of Contents](#)

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the NYSE American. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and it could be subject to sanctions or investigations by the NYSE American, the SEC or other regulatory authorities.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales, marketing and other personnel. We will be highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay, or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

We expect to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

As of June 30, 2025, we had a public float of less than \$250 million and therefore qualify as a smaller reporting company under the rules of the SEC as of the date of this annual report. As a smaller reporting company, we will be able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if it relies 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 more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than \$250.0 million. In that event, we could still be a smaller reporting company if our annual revenues were below \$100.0 million and we have a public float of less than \$700.0 million.

Changes in tax laws may materially adversely affect our business, prospects, financial condition and operating results.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business, prospects, financial condition and operating results. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act, the CARES Act, One Big Beautiful Bill Act and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the IRS and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Such tax law changes could have a material adverse impact on us. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. While it is too early to assess the overall impact of these changes, as these and other tax laws and related regulations are revised, enacted, and implemented, our financial condition, results of operations, and cash flows could be materially adversely impacted.

[Table of Contents](#)

Our ability to use net operating loss (NOL) carryforwards and other tax attributes may be limited, including as a result of the Merger.

We have incurred losses during our history, and we do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. As of December 31, 2025, we had U.S. federal NOL carryforwards of \$106.8 million, which will begin to expire in 2027 and \$82.8 million that have an unlimited carryforward period. Additionally, for state income tax purposes, we had NOLs of \$94.2 million that will expire at various dates between 2026 and 2045. The state of California suspended the use of NOL deductions for the tax years 2024 through 2026 if their California taxable income is greater than or equal to \$1 million. The state of California also limited the use of research and development credits to \$5 million for tax years 2024 through 2026. Under current law, U.S. federal NOL carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An “ownership change” pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including changes in connection with the Merger, changes in connection with the sale of our common stock, and other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

Conflicts of interest may arise from our relationship with Juvenescence, which will own a significant percentage of our common stock as well as warrants to purchase additional shares of our common stock and will be able to substantially influence the Company and exert control over matters subject to stockholder approval.

As of March 1, 2026, Juvenescence Limited (“Juvenescence”) owned approximately 33.0% of the outstanding shares of our common stock, including shares issuable upon exercise of warrants held by Juvenescence.

One member of our Board is the Executive Chairman and Co-Founder of Juvenescence and another member of our Board is the Chief Executive Officer of Juvenescence. Based on Juvenescence’s ownership of shares of our common stock, Juvenescence will be able to substantially influence us and exert control over matters subject to stockholder approval, the elections of directors, approval of our equity incentive plans, amendments to our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction.

Juvenescence’s interests may not always coincide with our corporate interests or the interests of our other stockholders, and we may exercise our voting and other rights in a manner with which other stockholders may not agree or that may not be in our best interests or the best interests of our stockholders other than Juvenescence. So long as Juvenescence owns a significant amount of our equity, it will be able to strongly influence our decisions. While the directors affiliated with Juvenescence will be obligated to act in accordance with their fiduciary duty, they may have equity or other interests in Juvenescence and, accordingly, their interests may be aligned with Juvenescence’s interests, which may not always coincide with our corporate interests or the interests of our other stockholders.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 1C. Cybersecurity

We have implemented cybersecurity measures and processes to address and mitigate material risks from cybersecurity threats. We utilize the services of third-party providers to develop, maintain, and implement cybersecurity systems and measures designed to protect our information systems from unauthorized access and damage. Our security measures are periodically assessed, tested, and updated. We do not have employees with information technology or cybersecurity expertise and accordingly we obtain an assessment of our cybersecurity systems and measures from a third-party provider different from the provider that is primarily responsible for installation, update, and maintenance of information technology and cyber security systems. Our information technology and cybersecurity service providers primarily interface with

[Table of Contents](#)

members of our accounting and finance group. These processes are an integral part of our internal controls and risk management and the results of the third-party assessment are reported annually to the Audit Committee along with a report from management on the effectiveness of internal controls.

We are not aware of the occurrence of any cybersecurity incidents that have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition. However, there can be no assurance that material cybersecurity incidents will not arise or be discovered in the future.

Item 2. Properties

Our principal place of business is located in Huntsville, Alabama where we lease approximately 7,600 square feet of office and laboratory space. Our office space lease expires on October 31, 2028, with options to renew, and our laboratory space lease expires on January 31, 2028. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms as needed.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims that arise in the ordinary course of business. As of the date of this report, we are not currently a party to any material legal proceedings.

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 is currently listed on the NYSE American under the symbol “SER.”

Holders of Record

As of March 1, 2026 there were 96 holders of record of our common stock.

Equity Compensation Plan

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	3,034,443	\$ 5.21	868,629
Equity compensation plans not approved by security holders	122,250	\$ 4.45	877,750
Total	3,156,693	\$ 5.18	1,746,379

Unregistered Sales of Equity Securities

Previously reported.

Repurchases of Equity Securities

None.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our Board of Directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing

Item 6. Reserved

Not applicable.

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

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the years ended December 31, 2025 and 2024.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. “Risk Factors” in this Annual Report.

Overview

We are a clinical-stage biotechnology company developing a pipeline of wholly owned drug product candidates to treat neurological diseases and other indications. Our POZ platform provides the potential to improve the integrated efficacy and safety profile of multiple modalities including small molecules, RNA-based therapeutics and antibody-based drug conjugates (ADCs). Our proprietary POZ technology is based on a synthetic, water soluble, low viscosity polymer called poly(2-oxazoline). Our POZ technology is engineered to provide greater control in drug loading and more precision in the rate of release of attached drugs. The therapeutic agents in our product candidates are typically well-understood and marketed drugs that are effective but are limited by pharmacokinetic profiles that can include toxicity, side effects and short half-life. We believe that by using POZ technology, drugs with narrow therapeutic windows can be designed to maintain more desirable and stable levels in the blood.

On March 26, 2024, we completed a merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of August 29, 2023 (the “Merger Agreement”), by and among AgeX, Canaria Transaction Corporation, an Alabama corporation and a wholly owned subsidiary of AgeX (“Merger Sub”), and Serina Therapeutics, Inc., an Alabama corporation (“Legacy Serina”), pursuant to which Merger Sub merged with and into Legacy Serina, with Legacy Serina surviving the merger as a wholly owned subsidiary of AgeX (the “Merger”). Additionally, on March 26, 2024, AgeX changed its name from “AgeX Therapeutics, Inc.” to “Serina Therapeutics, Inc.”

Following the consummation of the Merger, the business previously conducted by Legacy Serina became our business, which is now a clinical-stage biotechnology company developing Legacy Serina’s drug product candidates. Our headquarters are located in Huntsville, Alabama.

Since inception our operations have been financed primarily by aggregate net proceeds from the issuance of common stock, convertible preferred stock, convertible notes, exercise of Post-Merger Warrants to purchase our common shares by Juvenescence and our at-the-market (“ATM”) offerings. Since our inception, we have had significant operating losses. Our operating loss was \$24.0 million and \$17.0 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of \$63.5 million and cash and cash equivalents of \$3.1 million.

Our losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations within one year of our consolidated financial statements issuance date, raise substantial doubt about our ability to continue as a going concern. We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates and will require additional financing to continue this development.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, attorneys, and accountants and increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase significantly in connection with our ongoing activities as we:

- advance our lead product candidate, SER 252 into Phase I clinical trials;
- advance our other product candidates;
- advance our preclinical programs to clinical trials;
- further invest in our pipeline;
- seek regulatory approval for our investigational medicines;
- maintain, expand, protect, and defend our intellectual property portfolio;
- secure facilities to support continued growth in our research, development, and commercialization efforts; and
- increase our headcount to support our development efforts and to expand our clinical development team.

We have not had any products approved for sale. We do not expect to generate any product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. If we obtain

[Table of Contents](#)

regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses, or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce, or terminate planned activities to reduce costs.

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual conditions may differ from our assumptions and actual results may differ from our estimates.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Research and Development Costs

We will incur substantial expenses associated with manufacturing, preclinical research, and clinical studies. Accounting for preclinical research and clinical studies relating to activities performed by CROs, and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical research, clinical studies, and contract manufacturing activities. The diverse nature of services being provided under CROs and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain preclinical and clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with preclinical research and clinical studies. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued expenses or prepaid expenses on the consolidated balance sheets and within research and development expense on the consolidated statements of operations and comprehensive loss. In estimating the duration of a clinical study, we evaluate the start up, treatment and wrap up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Stock based Compensation

We have issued equity-based compensation awards through the granting of options. We account for equity-based compensation in accordance with Accounting Standards Codification ("ASC") 718, *Compensation—Stock Compensation*, ("ASC 718"). In accordance with ASC 718, compensation cost is measured at estimated fair value at grant date and is included as compensation expense over the vesting period during which service is provided in exchange for the award. Compensation cost of awards that contain a performance condition is recognized when achievement of the performance condition is considered probable during the performance period. Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the use of highly subjective assumptions, including the expected life of the stock-based payment awards and stock price volatility.

[Table of Contents](#)

We estimate the grant date fair value of stock options and the related compensation expense, using the Black-Scholes-Merton option valuation model. This option valuation model requires the input of subjective assumptions including: (1) expected life (estimated period of time outstanding) of the options granted, (2) volatility, (3) risk-free rate and (4) dividends. In general, the assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

Accounting for warrants

We have determined the accounting classification of warrants we issue, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, thereby obligating us to settle the warrants or the underlying shares by paying cash or other assets, or warrants that must or may require settlement by issuing a variable number of shares. If warrants do not meet liability classification under ASC 480-10, we assess the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, and in order to conclude equity classification, we also assess whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable U.S. GAAP. After all relevant assessments, we conclude whether the warrants are classified as liability or equity. Liability classified warrants are recorded at fair value upon issuance and subsequently remeasured to fair value each reporting period until settlement with all changes in fair value recorded in the consolidated statements of operations and comprehensive loss. Equity classified warrants are recorded at fair value upon issuance and are not subsequently remeasured. We estimate the fair value of warrants using the Black-Scholes-Merton option pricing model. See Notes 5, *Related Party Transactions*, 6, *Fair Value Measurements*, for additional information regarding the warrants and 7, *Stockholders' (Deficit) Equity*.

Components of Operating Results

Grant Revenues

Our grants and contracts reimburse us for direct and indirect costs relating to the grant projects and also provide us with a pre-negotiated profit margin on total direct and indirect costs of the grant award, excluding subcontractor costs, after giving effect to directly attributable costs and allowable overhead costs. Funds received from grants and contracts are generally deemed to be earned and recognized as revenue as allowable costs are incurred during the grant or contract period and the right to payment is realized.

Operating Expenses

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

Research and Development

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

- personnel costs, which include salaries, benefits and equity-based compensation expense;
- expenses incurred under agreements with consultants and contract organizations that conduct research and development activities on our behalf;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials; and
- facility related costs, laboratory supplies and equipment used for internal research and development activities.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and service providers.

Our research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates and therefore have not implemented the systems and procedures to track research and development expenses on a program-by-program basis. We track research and development expenses based on the type of expense as further described below under “Results of Operations – *Research and Development Expenses*.” Substantially all our historical research and development costs were incurred in the development of our preclinical candidates and advancing research on our POZ lipid technology.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in conducting clinical trials, manufacturing and otherwise advancing our programs. The process of conducting the clinical research necessary to obtain regulatory approval is costly and time consuming, and the successful development of our product candidates is highly uncertain.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing, and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of any of our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of preclinical studies and initiation of clinical trials for future product candidates;
- successful enrollment and completion of clinical trials for our current product candidates;
- data from our clinical programs that support an acceptable risk benefit profile of our product candidates in the intended patient populations; acceptance by the U.S. Food and Drug Administration (“FDA”), or other applicable regulatory agencies of the Investigational New Drug (“IND”) applications, clinical trial applications and/or other regulatory filings for SER 252 and other product candidates.

[Table of Contents](#)

- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- making of arrangements with contract manufacturing organizations for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing, and adequate reimbursement from third party payors, including government payors;
- maintenance, enforcement, defense, and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation, or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay, or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development. On November 3, 2025, we announced that we received a notice from the FDA, placing a clinical hold on our IND application for SER-252, our lead development program for advanced Parkinson's disease. The FDA requested additional information related to a commonly used excipient in the formulation of SER-252. The FDA's feedback did not relate to the active drug substance or its proposed mechanism of action. In January 2026, we announced that the FDA had cleared its IND application for SER-252, which allowed us to proceed with regulatory and site-level activities to support initiation of a planned Phase 1b registrational clinical study evaluating SER-252 in patients with advanced Parkinson's disease and in February 2026 we enrolled and dosed our first patient into the clinic.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing SER 252 and our other product candidates through clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, and other expenses for outside professional services, including legal, recruiting, audit and accounting, insurance and facility related costs not otherwise included in

[Table of Contents](#)

research and development expenses. Personnel costs consist of salaries, benefits and equity-based compensation expense for our personnel in executive and other administrative functions. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating as a public company. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory, and other fees and services associated with maintaining compliance with the New York Stock Exchange American Company Guide and SEC requirements, director and officer insurance costs, and investor relations costs associated with being a public company.

Other Income/(Expense)

Our other income/(expenses) are comprised of interest income on our cash equivalents, changes in fair value of our convertible notes and liability-classified warrants, interest accrued from the convertible notes and foreign currency transaction gains/(losses).

Results of Operations

Comparison of Years Ended December 31, 2025 and 2024

The table presented below shows Net Loss for the periods presented (in thousands).

	Year Ended December 31,		Increase/ (Decrease)
	2025	2024	
REVENUES			
Grant revenues	\$ 130	\$ 56	\$ 74
Total revenues	130	56	74
OPERATING EXPENSES			
Research and development	13,155	7,480	5,675
General and administrative	10,997	9,624	1,373
Total operating expenses	24,152	17,104	7,048
Total other income, net	4,825	5,841	(1,016)
Provision for income taxes	18	—	18
NET LOSS	\$ (19,215)	\$ (11,207)	\$ (8,008)

Research and Development Expenses

Research and development expenses were \$13.2 million for the year ended December 31, 2025, compared to \$7.5 million for the same period in 2024. The increase of \$5.7 million was primarily due to increases of \$2.0 million in clinical related activities, \$1.4 million in salaries, payroll related expenses and stock based compensation as a result of increased headcount, \$1.0 million in consultant spend for research programs, amortization of \$0.7 million for a prepaid technology access fee, \$0.6 million increased spend in outsourced research services and \$0.3 million in miscellaneous expenses amounts that were individually insignificant. These increases were primarily offset by a decrease of \$0.3 million for severance and related costs.

General and Administrative Expenses

General and administrative expenses were \$11.0 million for the year ended December 31, 2025, compared to \$9.6 million for the same period in 2024. The increase of \$1.4 million is due primarily to increases of \$1.2 million in stock based compensation expense as a result of new hires, directors and consultants, \$0.6 million of consulting expenses for public company infrastructure, \$0.4 million in investor outreach activities and an increase of \$0.1 million in miscellaneous expenses amounts that were individually insignificant. These increases were primarily offset by decreases of \$0.6 million

[Table of Contents](#)

in legal fees and professional fees for the maintenance of certain patent and other intellectual property and biological material assets included in Legacy Assets and \$0.3 million in severance and related costs.

See Notes 1, *Organization, Business Overview and Liquidity* and 5, *Related Party Transactions* to our audited consolidated financial statements included elsewhere in this Report for additional information about the Legacy Assets.

Other Income, net

Other income, net was \$4.8 million for the year ended December 31, 2025, compared to \$5.8 million for the same period in 2024. The \$1.0 million decrease is primarily attributable to a decrease in gain of \$8.9 million from the change in fair value of liability classified warrants and a \$0.2 million loss from the sale of a subsidiary. These decreases were partially offset by the absence in 2025 of a \$7.0 million loss recognized in 2024 from the change in the fair value of the Legacy Serina Convertible Notes and the AgeX-Serina Note, a \$0.7 million gain from the expiration of liability classified warrants, a decrease of \$0.3 million in interest expense and \$0.1 million decrease in miscellaneous expenses amounts that were individually insignificant.

See Notes 6, *Fair Value Measurements* and 7, *Stockholders' (Deficit) Equity* to our consolidated financial statements included elsewhere in this Report for additional information on fair value adjustments of convertible promissory notes, Legacy Serina warrants, liability classified Warrants, and conversion of the AgeX-Serina Note upon consummation of the Merger on March 26, 2024.

Liquidity and Capital Resources

Sources of Liquidity

We had \$3.1 million in cash and cash equivalents as of December 31, 2025. Our operations have been financed primarily by the issuance of common stock, convertible preferred stock, convertible notes, warrant exercises and our ATM program.

In April 2025, we entered into a Securities Purchase Agreement with certain investors for a private placement of securities. At the closing of the Private Placement, we issued an aggregate of 965,250 shares of newly authorized Series A Convertible Preferred Stock, par value \$0.0001, at a purchase price of \$5.18 per share, resulting in net proceeds of \$4.9 million. Each share of Series A Preferred Stock is convertible into shares of our common stock, par value (\$0.0001), at a conversion price of \$5.18 per share, subject to adjustment upon consummation of certain qualified offering events and other standard adjustments due to subdivision or combination of common stock, and earns cumulative annual dividend at a rate of 8% per annum that are declared annually beginning on March 31, 2026 and paid in shares of the Company's common stock ("PIK Shares"). As of December 31, 2025, 56,645 dividend shares have been accrued but not declared.

Additionally, on April 25, 2025, we entered into a sales agreement (the "Sales Agreement") with JonesTrading Institutional Services LLC (the "Sales Agent"), with respect to an ATM program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$13.3 million through the Sales Agent. We pay the Sales Agent a commission up to 3.0% of the gross sales proceeds of any shares sold under the Sales Agreement. In 2025, we have sold 0.5 million shares of our common stock at an gross average price of \$6.00, resulting in gross proceeds of \$2.8 million under the ATM. To date, we have issued 3.5 million shares of common stock under the ATM program at a gross average per share price of \$3.72, resulting in gross proceeds of \$12.9 million.

Annual 2025 Operating Results

On September 9, 2025, we entered into an unsecured convertible note (the "2025 Convertible Note") with a member of our Board of Directors, making available to Serina an aggregate principal amount of up to \$20 million. The 2025 Convertible Note was subsequently modified in March 2026. See in paragraph below and in Note 14, *Subsequent Events* to our consolidated financial statement for details. Under the original 2025 Convertible Note, borrowings may be drawn at our discretion in five tranches tied to certain clinical and operational milestones, provided that if at the time we achieve a milestone and do not have sufficient cash available to cover projected costs and expenses to achieve the next milestone, then we will be required to draw such deficiency. The five tranches correspond to the five following milestones: (i) up to \$5 million on or before September 30, 2025; (ii) up to \$2.5 million on or after December 15, 2025 upon enrollment of the first patient in the our SER-252-1b registrational clinical study; (iii) up to \$2.5 million upon enrollment of the second patient in the study; (iv) up to \$5 million on or after March 15, 2026, upon dosing of the last patient in Cohort 1 of the study; and (v) up to \$5 million on or after April 30, 2026, upon dosing of the first patient in Cohort 2 of the study

[Table of Contents](#)

("Milestone 5"). See the section entitled "Components of Operating Results" above for a discussion of the impact of recent FDA communication on the clinical study.

The 2025 Convertible Note was convertible, at the option of the holder, into shares of our common stock, at any time until the maturity date, at a conversion price of \$5.18 per share. The conversion price was subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization, or other similar transaction. In September 2025, we drew down the first tranche of \$5.0 million under the 2025 Convertible Note, incurring \$0.1 million in transaction costs which were accounted for as a debt discount.

On March 17, 2026, we entered into definitive agreements for the private placement of common stock and pre-funded warrants, led by a member of the Company's Board of Directors, at \$2.25 per share. Each common stock and pre-funded warrant was accompanied by redeemable warrants to purchase a number of shares equal to 50% of the aggregate shares purchased at an exercise price of \$5.00 per share. All warrants expire four years term from the date of issuance and are callable by us upon the earlier of (i) 30 days following the dosing of the first patient in Cohort 2 of the SER-252 Phase 1b SAD study, or (ii) September 30, 2026, and in each case subject to the Company's share price exceeding \$10.00 per share on the relevant date. Under the terms of the agreements, the initial funding provided for at least \$15.0 million of gross proceeds, with one or more additional closings for aggregate gross proceeds of at least \$5.0 million and up to \$15.0 million to be funded within 20 days after the initial closing, subject to the satisfaction of customary closing conditions. The warrants related to the first tranche funding, if fully exercised, would provide additional gross cash proceeds of \$33.3 million. As of March 23, 2026, gross proceeds of \$16.0 million have been received. In connection with the closing of the private placement, the 2025 Convertible Note was amended to remove any further obligations to borrow or loan funds under the note.

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Since inception, we have had significant operating losses and negative cash flows and as of December 31, 2025, had an accumulated deficit of \$63.5 million. Our losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations within one year of the issuance date of our consolidated financial statements included in this Report, raise substantial doubt about our ability to continue as a going concern. We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates and will require additional financing to continue this development. Our consolidated financial statements have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

The unavailability or inadequacy of financing to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of planned operations.

Funding Requirements

Any product candidates we may develop may never achieve commercialization, and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. Our primary uses of capital are, and we expect will continue to be, costs related to pre-clinical and clinical research, clinical studies, manufacturing, and development services; laboratory expenses and costs for related supplies; compensation and related expenses; license payments or milestone obligations that may arise; legal and other regulatory expenses and general overhead costs.

We believe that our cash on hand will not be sufficient to enable us to fund our operations at least twelve months following the issuance of the consolidated financial statements based on our current plan. To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings, our ATM, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or

[Table of Contents](#)

private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce, or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, costs and results of IND enabling studies for our lead product candidate SER 252 and our potential future clinical trials for SER 252;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient ("API") and manufacture of our product candidates and the terms of such arrangements;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any; the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing, and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property related claims;
- the extent to which we acquire or in license other products, product candidates, technologies, or data referencing rights;
- the ability to receive additional nondilutive funding, including grants from organizations and foundations; and
- the costs of operating as a public company

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

[Table of Contents](#)

Summary of Cash Flows

The following table summarizes the major sources and uses of cash for the periods set forth below (in thousands):

	Year Ended December 31,		\$ Change	% Change
	2025	2024		
Net cash used in operating activities	\$ (17,955)	\$ (17,137)	\$ (818)	4.8%
Net cash used in investing activities	(59)	(22)	(37)	168.2 %
Net cash provided by financing activities	17,412	13,212	4,200	31.8 %
Effect of foreign currency on cash and cash equivalents	(14)	—	(14)	100.0 %
Net decrease in cash and cash equivalents	<u>\$ (616)</u>	<u>\$ (3,947)</u>	<u>\$ 3,331</u>	<u>(84.4)%</u>

Operating Activities

Net loss for the year ended December 31, 2025 was \$19.2 million. Net cash used in operating activities during this period amounted to \$18.0 million. The \$1.2 million difference between the net loss and net cash used in operating activities during the year ended December 31, 2025 was comprised of offsetting non-cash items of \$0.2 million and changes in operating assets and liabilities totaling \$1.4 million. The non-cash items consisted of \$4.0 million in stock-based compensation and equity compensation to consultants for services, \$0.2 million in non-cash lease expenses, \$0.2 million loss on sale of subsidiary, \$0.2 million in non-cash interest, \$0.1 million loss in disposal of property and equipment and \$0.1 million non-cash change in miscellaneous expenses that were individually insignificant. These non-cash items were reduced by the non-cash gain of \$4.3 million from the change in the fair value of warrants and \$0.7 million gain from warrant expirations. The net increase of \$1.4 million cash from operating assets and liabilities primarily consisted of a \$1.2 million increase in accounts payable and decrease of \$0.7 million in prepaid and other current assets. These cash increases were partially offset by a \$0.2 million decrease in accrued expenses and \$0.1 million decrease in grant receivable.

Net loss for the year ended December 31, 2024 was \$11.2 million. Net cash used in operating activities during this period totaled \$17.1 million. The \$5.9 million difference between the net loss and net cash used in operating activities during the year ended December 31, 2024 was driven by \$2.7 million in non-cash items and \$3.3 million in changes to operating assets and liabilities. The net \$2.7 million in non-cash items consisted of a \$13.2 million gain from the change in the fair value of warrant liabilities which were partially offset by a \$7.0 million loss from the change in fair value of convertible notes, \$2.6 million in stock-based compensation, \$0.3 million in amortization of deferred debt issuance costs, a \$0.2 million decrease in accrued interest on the AgeX-Serina Note and \$0.4 million in depreciation and non-cash lease expenses. The \$3.3 million net cash used in operating assets and liabilities primarily consisted of a \$1.8 million increase in prepaid expenses (comprised of \$1.1 million in other prepaid expenses and current assets, and \$0.7 million in prepaid technology access fee) along with payments of \$1.7 million towards accounts payable and \$0.2 million in lease liabilities. These outflows were partially offset by a \$0.4 million increase in accrued expenses.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2025 and 2024 was immaterial.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 of \$17.4 million was primarily due to net proceeds received of \$4.9 million from issuance of common stock to Juvenescence in January 2025, \$4.9 million received in April 2025 from a securities purchase agreement entered into with certain investors for a private placement of securities, net proceeds received of \$4.9 million from the first tranche drawdown under the 2025 Convertible Note and \$2.6 million net proceeds from our ATM. See Note 7, *Stockholders' (Deficit) Equity*, to our consolidated financial statements included elsewhere in this Report for additional information.

Net cash provided by financing activities for the year ended December 31, 2024 of \$13.2 million was primarily attributable to \$5.0 million in proceeds received from the exercise of 377,865 Post-Merger Warrants by Juvenescence, \$5.0 million received from issuance of common stock to Juvenescence in November 2024, \$3.0 million drawn under the loan facilities

[Table of Contents](#)

from Juvenescence, and \$0.3 million cash and restricted cash acquired in connection with the Merger. These changes were partially offset by \$0.1 million repayment of principal on loan facilities to Juvenescence.

See Note 5, *Related Party Transactions*, to our consolidated financial statements included elsewhere in this Report for additional information about the related party transactions with Juvenescence.

Off-Balance Sheet Arrangements

As of December 31, 2025, we did not have any off-balance sheet arrangements, as defined in Item 303(a) (4) (ii) of SEC Regulation S-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not required for smaller reporting companies.

[Table of Contents](#)

Item 8. Financial Statements and Supplementary Data

**Serina Therapeutics, Inc.
Index to Consolidated Financial Statements**

	Page Number
Report of Independent Registered Public Accounting Firm (PCAOB ID: 215)	89
Audited Consolidated Financial Statements:	
Consolidated Balance Sheets	90
Consolidated Statements of Operations	91
Consolidated Statements of Comprehensive Loss	92
Consolidated Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity	93
Consolidated Statements of Cash Flows	94
Notes to Consolidated Financial Statements	96

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Serina Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Serina Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' (deficit) equity, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as December 31, 2025 and 2024, and the results of its operations and cash flows for the years then ended, 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 financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has losses from operations, negative operating cash flows, accumulated deficit, and additional capital needs. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Frazier & Deeter, LLC

We have served as the Company's auditor since 2021.

Tampa, Florida

March 25, 2026

[Table of Contents](#)

SERINA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value amounts)

	December 31,	
	2025	2024
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,056	\$ 3,672
Prepaid expenses and other current assets	3,024	2,004
Total current assets	6,080	5,676
Property and equipment, net	465	501
Right of use assets - operating leases	377	461
Right of use assets - finance leases	—	86
Other long-term prepaid assets	29	—
TOTAL ASSETS	\$ 6,951	\$ 6,724
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 1,931	\$ 744
Accrued expenses	1,207	1,429
Warrant liability	88	—
Other current liabilities	337	193
Total current liabilities	3,563	2,366
Warrant liability, non-current	283	3,582
Convertible Note, net	2,946	—
Operating lease liabilities, net of current portion	196	268
TOTAL LIABILITIES	6,988	6,216
Commitments and contingencies (Note 11)		
Stockholders' (deficit) equity:		
Series A convertible preferred stock, \$0.0001 par value, 5,000 shares authorized; 965 and zero shares issued and outstanding at December 31, 2025 and 2024, respectively; liquidation preference of \$5,000 and zero at December 31, 2025 and 2024, respectively;	4,940	—
Common stock, \$0.0001 par value, 40,000 shares authorized; and 10,767 and 9,422 shares issued and outstanding at December 31, 2025 and 2024, respectively; (including 57 shares declared as a stock dividend on April 1, 2025 and issued on March 31, 2026)	1	1
Additional paid-in capital	58,536	44,958
Accumulated other comprehensive loss	(14)	—
Accumulated deficit	(63,500)	(44,318)
Total Serina Therapeutics, Inc. stockholders' (deficit) equity	(37)	641
Noncontrolling deficit	—	(133)
TOTAL STOCKHOLDERS' (DEFICIT) EQUITY	(37)	508
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	\$ 6,951	\$ 6,724

See accompanying notes to the consolidated financial statements.

SERINA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year Ended December 31,	
	2025	2024
REVENUES		
Grant revenues	\$ 130	\$ 56
Total revenues	130	56
OPERATING EXPENSES		
Research and development	13,155	7,480
General and administrative	10,997	9,624
Total operating expenses	24,152	17,104
Loss from operations	(24,022)	(17,048)
OTHER INCOME, NET		
Interest expense	(213)	(526)
Change in fair value of convertible promissory notes	—	(7,017)
Change in fair value of warrants liabilities	4,263	13,156
Gain on warrants expiration	724	—
Other income, net	51	228
Total other income, net	4,825	5,841
Loss before income taxes	(19,197)	(11,207)
Provision for income taxes	(18)	—
NET LOSS	(19,215)	(11,207)
Net loss attributable to noncontrolling interest	33	66
NET LOSS ATTRIBUTABLE TO SERINA	\$ (19,182)	\$ (11,141)
NET LOSS ATTRIBUTABLE TO SERINA COMMON STOCKHOLDERS	\$ (19,436)	\$ (11,141)
NET LOSS ATTRIBUTABLE TO SERINA COMMON SHAREHOLDER, BASIC AND DILUTED	\$ (1.91)	\$ (1.51)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING, BASIC AND DILUTED	10,190	7,359

See accompanying notes to the consolidated financial statements.

SERINA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,	
	2025	2024
NET LOSS	\$ (19,215)	\$ (11,207)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustment	(14)	—
COMPREHENSIVE LOSS	(19,229)	(11,207)
Net loss attributable to noncontrolling interest	33	66
COMPREHENSIVE LOSS ATTRIBUTABLE TO SERINA	<u>\$ (19,196)</u>	<u>\$ (11,141)</u>

See accompanying notes to the consolidated financial statements.

SERINA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY
(In thousands)

	Redeemable Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Deficit	Total Stockholders' (Deficit) Equity
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Par Value					
BALANCE AT DECEMBER 31, 2023	3,438	\$ 36,404	—	—	2,410	\$ —	\$ 883	\$ —	\$ (33,177)	\$ —	\$ (32,294)
Issuance of common stock upon exercise of stock options	—	—	—	—	195	—	12	—	—	—	12
Issuance of common stock upon conversion of redeemable convertible preferred stock	(3,438)	(36,404)	—	—	3,438	1	36,403	—	—	—	36,404
Issuance of common stock to AgeX stockholders and conversion of AgeX-Serina Note upon consummation of Merger	—	—	—	—	2,501	—	961	—	—	—	961
Issuance of common stock upon exercise of Post-Merger Warrants	—	—	—	—	378	—	6,360	—	—	—	6,360
Deemed dividend from issuance of warrants	—	—	—	—	—	—	(18,501)	—	—	—	(18,501)
Issuance of common stock to Juvenescence	—	—	—	—	500	—	5,392	—	—	—	5,392
Sale of subsidiary to Juvenescence	—	—	—	—	—	—	10,853	—	—	(67)	10,786
Stock-based compensation	—	—	—	—	—	—	2,595	—	—	—	2,595
Net loss	—	—	—	—	—	—	—	—	(11,141)	(66)	(11,207)
BALANCE AT DECEMBER 31, 2024	—	—	—	—	9,422	1	44,958	—	(44,318)	(133)	508
Issuance of common stock upon exercise of stock options	—	—	—	—	260	—	15	—	—	—	15
Issuance of common stock to Juvenescence, net of issuance costs of \$83	—	—	—	—	500	—	4,916	—	—	—	4,916
Issuance of common stock for Series A Convertible Preferred Stock, net of issuance costs of \$60	—	—	965	4,940	—	—	—	—	—	—	4,940
Issuance of common stock under At-The-Market sales agreement, net of issuance costs of \$212	—	—	—	—	473	—	2,628	—	—	—	2,628
Issuance of common stock to consultant for services rendered	—	—	—	—	50	—	226	—	—	—	226
Release of restricted stock units to consultant for services rendered	—	—	—	—	5	—	29	—	—	—	29
Reclassification of warrant liability to equity	—	—	—	—	—	—	1,971	—	—	—	1,971
Sale of NeuroAirmid subsidiary	—	—	—	—	—	—	—	—	—	166	166
Issuance of common stock for Series A Convertible Preferred stock dividends	—	—	—	—	57	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	3,793	—	—	—	3,793
Foreign currency translation adjustment	—	—	—	—	—	—	—	(14)	—	—	(14)
Net loss	—	—	—	—	—	—	—	—	(19,182)	(33)	(19,215)
BALANCE AT DECEMBER 31, 2025	—	\$ —	965	\$ 4,940	10,767	\$ 1	\$ 58,536	\$ (14)	\$ (63,500)	\$ —	\$ (37)

See accompanying notes to the consolidated financial statements.

SERINA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2025	2024
OPERATING ACTIVITIES:		
Net loss	\$ (19,215)	\$ (11,207)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	73	194
Loss on disposal of property and equipment	91	—
Non-cash lease expense	203	227
Non-cash interest expense	138	164
Amortization of debt issuance costs and debt discounts	58	345
Stock-based compensation	3,793	2,595
Common stock issued to consultant for services rendered	226	—
Restricted stock units released to consultant for services rendered	29	—
Change in fair value of convertible promissory notes	—	7,017
Change in fair value of warrants liabilities	(4,263)	(13,156)
Gain on warrants expiration	(724)	—
Loss on sale of subsidiary	166	—
Changes in operating assets and liabilities:		
Grant receivable	—	65
Prepaid expenses and other assets	673	(1,906)
Accounts payable	1,197	(1,661)
Accrued expenses	(231)	400
Other current liabilities	18	—
Operating lease liabilities	(187)	(214)
Net cash used in operating activities	<u>(17,955)</u>	<u>(17,137)</u>
INVESTING ACTIVITIES:		
Purchase of equipment	(59)	(22)
Net cash used in investing activities	<u>(59)</u>	<u>(22)</u>
FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock and warrants to Juvenescence	—	5,000
Drawdown on loan facilities from Juvenescence	—	3,043
Cash and restricted cash acquired in connection with the Merger	—	337
Proceeds from the exercise of stock options	15	12
Proceeds from the exercise of Post-Merger Warrants by Juvenescence	—	4,988
Proceeds from issuance of common stock to Juvenescence, net	4,916	—
Principal repayment on loan facilities to Juvenescence	—	(133)
Principal repayments on finance lease liabilities	—	(35)
Proceeds from issuance of Series A Convertible Preferred Stock, net	4,940	—
Proceeds from issuance of common stock under At-The-Market sales agreement, net	2,628	—
Proceeds from 2025 Convertible Note, net	4,913	—
Net cash provided by financing activities	<u>17,412</u>	<u>13,212</u>
Effect of foreign currency on cash and cash equivalents	(14)	—
NET DECREASE IN CASH AND CASH EQUIVALENTS	<u>(616)</u>	<u>(3,947)</u>
CASH AND CASH EQUIVALENTS:		

[Table of Contents](#)

At beginning of the year		3,672	7,619
At end of the year	\$	3,056	\$ 3,672
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for interest	\$	17	\$ —
SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES:			
Issuance of common stock upon conversion of redeemable convertible preferred stock	\$	—	\$ 36,404
Merger and issuance of common stock upon consummation of Merger on March 26, 2024	\$	—	\$ 961
Deemed dividend from issuance of warrants	\$	—	\$ 18,501
Derecognition of Post Merger and Incentive Warrants liability upon exchange transaction	\$	—	\$ (1,799)
Issuance of common stock warrants upon exchange transaction	\$	—	\$ 1,407
Issuance of common stock warrants upon exercise of Post-Merger warrants	\$	—	\$ 1,372
Extinguishment of debt upon sale of subsidiary	\$	—	\$ 10,786
Right of use asset acquired in exchange for operating lease liabilities	\$	115	\$ —
Transfer of right-of-use assets to property and equipment upon title transfer	\$	75	\$ —
Issuance of common stock warrants in connection with 2025 Convertible Note	\$	3,747	\$ —
Recognition of debt discount on 2025 Convertible Note	\$	2,112	\$ —
Reclassification of warrant liability to equity	\$	1,971	\$ —

See accompanying notes to the consolidated financial statements.

SERINA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization, Business Overview and Liquidity

Serina Therapeutics, Inc. was incorporated as AgeX Therapeutics, Inc. in January 2017 in the state of Delaware. On March 26, 2024, AgeX Therapeutics, Inc. ("AgeX") completed a merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of August 29, 2023 (the "Merger Agreement"), by and among AgeX, Canaria Transaction Corporation, an Alabama corporation and a wholly owned subsidiary of AgeX ("Merger Sub"), and Serina Therapeutics, Inc., an Alabama corporation ("Legacy Serina"), pursuant to which Merger Sub merged with and into Legacy Serina, with Legacy Serina surviving the merger as a wholly owned subsidiary of AgeX (the "Merger"). Additionally, on March 26, 2024, AgeX changed its name from "AgeX Therapeutics, Inc." to "Serina Therapeutics, Inc.". Unless otherwise stated or the context otherwise requires, together with its subsidiaries, "Serina" or the ("Company"). See Note 3, *Recapitalization*, for the accounting for the Merger.

Following the consummation of the Merger, the business previously conducted by Legacy Serina became the business conducted by the Company, which is now a clinical-stage biotechnology company developing Legacy Serina's drug product candidates. The Company's headquarters are located in Huntsville, Alabama.

The Company is a clinical-stage biotechnology company developing a pipeline of wholly-owned drug product candidates to treat neurological diseases and other indications. The Company's POZ drug delivery technology is designed to enable certain existing drugs and novel drug candidates to be modified in a way that provides the potential to improve the integrated efficacy and safety profile of multiple modalities including small molecules, RNA-based therapeutics, and antibody-based drug conjugates (ADCs). The Company's proprietary POZ technology is based on a synthetic, water soluble, low viscosity polymer called poly(2-oxazoline) and is engineered to provide greater control in drug loading and more precision in the rate of release of attached drugs delivered via easy-to-administer, long-acting subcutaneous injection.

The therapeutic agents in the Company's product candidates are typically well-understood and marketed drugs that are effective but are limited by pharmacokinetic (PK) profiles that can include toxicity, side effects and short half-life. The Company believes that by using POZ technology, drugs with narrow therapeutic windows can be designed to maintain more desirable and stable levels in the blood. The Company believes that POZ technology can be applied to small molecules, proteins, antibody drug conjugates, and other classes of molecules.

Prior to the closing of the Merger, any assets of AgeX other than certain "Legacy Assets" were transferred into a newly formed subsidiary of AgeX, UniverXome Bioengineering, Inc. ("UniverXome"). UniverXome assumed (i) any outstanding indebtedness of AgeX to Juvenescence Limited ("Juvenescence"), which was secured by the assets contributed to UniverXome, (ii) most of the Company's contracts with third parties, other than certain designated contracts and any contracts that were terminated before the Merger, and (iii) all other liabilities of the Company in existence as of the effective time of the Merger (other than certain transaction expenses related to the Merger). In December 2024, the Company sold UniverXome to Juvenescence. See Note 5, *Related Party Transactions*.

Liquidity and Going Concern

In addition to general economic and capital market trends and conditions, the Company's ability to raise sufficient additional capital to finance its operations from time to time will depend on a number of factors specific to the Company's operations such as operating expenses and progress in out-licensing its technologies and development of its product candidates.

The unavailability or inadequacy of financing to meet future capital needs could force the Company to modify, curtail, delay, or suspend some or all aspects of planned operations. Sales of additional equity securities could result in the dilution of the interests of its stockholders. The Company cannot assure that adequate financing will be available on favorable terms, if at all.

The Company recognized a net loss of \$19.2 million for the year ended December 31, 2025. The Company used \$18.0 million in net cash from operating activities for the year ended December 31, 2025 and has historically incurred losses from operations and expects to continue to generate negative cash flows as the Company implements its business plan.

[Table of Contents](#)

Management believes that its cash and cash equivalents are not expected to be sufficient to satisfy the Company's anticipated operating and other funding requirements for the twelve months from the issuance of these consolidated financial statements. As such, there is substantial doubt about the Company's ability to continue as a going concern. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, technical risks associated with the successful research, development and manufacturing of therapeutic candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations. Therapeutic drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel, and infrastructure. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales. The Company expects to largely rely on raising capital from equity investors, and additional funding through the Company's at-the-market offering ("ATM"), for funding its operations. Some funding may be obtained through licensing agreements or other arrangements with commercial entities.

As a result of recurring losses from operations and recurring negative cash flows from operations, there is substantial doubt regarding the Company's ability to maintain liquidity sufficient to operate its business effectively. If sufficient capital is not available, the Company would be required to delay, limit, reduce, or terminate its product development or future commercialization efforts or grant rights to develop and market therapeutic candidates to other entities. There can be no assurance that the Company will be able to raise additional funds or that the terms and conditions of any future financings will be workable or acceptable to the Company or its shareholders. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classifications of liabilities that might be necessary should the Company be unable to continue as a going concern.

2. Basis of Presentation and Summary of Significant Accounting Policies

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries in which the Company has a controlling financial interest. The Company established Serina Therapeutics Australia Pty Ltd on July 2, 2025, for the purpose of conducting clinical research activities in Australia. For consolidated entities where the Company has less than 100% of ownership, the Company records net loss attributable to noncontrolling interest on the consolidated statement of operations equal to the percentage of the ownership interest retained in such entities by the respective noncontrolling parties. The noncontrolling interest is reflected as a separate element of stockholders' (deficit) equity on the Company's consolidated balance sheets. Any material intercompany transactions and balances have been eliminated upon consolidation.

The Company assesses whether it is the primary beneficiary of a variable interest entity ("VIE") at the inception of the arrangement and at each reporting date. This assessment is based on its power to direct the activities of the VIE that most significantly impact the VIE's economic performance and the Company's obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. If the entity is within the scope of the variable interest model and meets the definition of a VIE, the Company considers whether it must consolidate the VIE or provide additional disclosures regarding its involvement with the VIE. If the Company determines that it is the primary beneficiary of the VIE, the Company will consolidate the VIE. This analysis is performed at the initial investment in the entity or upon any reconsideration event. For entities the Company holds as an equity investment that are not consolidated under the VIE model, the Company will consider whether its investment constitutes a controlling financial interest in the entity and therefore should be considered for consolidation under the voting interest model.

Pursuant to a stock purchase agreement with Juvenescence, dated December 23, 2024, the Company sold all outstanding shares of UniverXome for a nominal cash payment and deconsolidated UniverXome. See Note 5, *Related Party Transactions* for details.

NeuroAirmid was jointly owned by the Company and certain researchers from the University of California and was organized to pursue certain cell therapies, focusing initially on Huntington's Disease. The Company owned 47.5% of the outstanding capital stock of NeuroAirmid. The Company consolidated NeuroAirmid despite not having majority ownership interest as it has the ability to influence decision making and financial results through contractual rights and obligations as per Accounting Standards Codification ("ASC") 810, *Consolidation*. On March 27, 2024, the Board of Directors of the Company formed a special committee for the purpose of exploring strategic alternatives for the business, assets and/or stock of UniverXome, Reverse Bio, ReCyte and NeuroAirmid. On October 28, 2025, the special committee of the Board of

[Table of Contents](#)

Directors approved the Company entering into a stock redemption agreement whereby NeuroAirmid redeemed the shares of NeuroAirmid capital stock held by the Company in exchange for the right to receive 5% of the net revenues recognized by NeuroAirmid in connection with the sale, lease, license, transfer, distribution or use of any products, assets or services of NeuroAirmid developed or commercialized for the purpose of treating Huntington's Disease (the "NeuroAirmid Transaction"). The NeuroAirmid Transaction was completed on November 25, 2025 and NeuroAirmid was subsequently deconsolidated with an immaterial impact on the Company's financial statements.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect (i) the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and (ii) the reported amounts of revenues and expenses during the reporting period, in each case with consideration given to materiality. Significant estimates and assumptions which are subject to significant judgment include those related to assumptions used to value stock-based awards and liability classified warrants. Actual results could differ materially from those estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash equivalents. The Company maintains its cash deposits in Federal Deposit Insurance Corporation ("FDIC") insured financial institutions and may at times hold investments at Securities Investor Protection Corporation ("SIPC") insured broker-dealers.

The balances in these accounts may be in excess of FDIC and SIPC insured limits. At December 31, 2025 and 2024, cash and cash equivalents deposits in excess of FDIC limits were both nominal, and investments and deposits in excess of SIPC limits were \$2.5 million and \$2.9 million, respectively.

Product candidates developed by the Company and its subsidiaries will require approvals or clearances from the United States Food and Drug Administration ("FDA") or foreign regulatory agencies prior to commercial sales. There can be no assurance that any of the product candidates being developed or planned to be developed by the Company or its subsidiaries will receive any of the required approvals or clearances. If regulatory approval or clearance were to be denied or any such approval or clearance was to be delayed, it would have a material adverse impact on the Company.

Foreign currency translation and transactions

The Company's reporting currency is the U.S. dollar. The functional currency of the Company's subsidiary located in Australia is the Australian Dollar. Balance sheets prepared in the functional currencies are translated to the reporting currency at exchange rates in effect at the end of the accounting period, except for stockholders' (deficit) equity accounts, which are translated at rates in effect when these balances were originally recorded. Revenue and expense accounts are translated using an average exchange rate during the year. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive loss in the accompanying consolidated balance sheets. Gains and losses resulting from exchange rate changes on transactions denominated in a currency other than the functional currency are included in earnings as incurred.

Fair value measurements of financial instruments

The Company has adopted ASC Topic 820, *Fair Value Measurement*, for certain financial instruments measured as fair value on a recurring basis. ASC Topic 820 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC Topic 820 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value.

The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements).

The three levels of inputs that may be used to measure fair value are as follows:

- Level 1: Quoted prices in active markets for identical assets or liabilities.

[Table of Contents](#)

- Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets with insufficient volume or infrequent transactions (less active markets), or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated with observable market data for substantially the full term of the assets or liabilities. Level 2 inputs also include non-binding market consensus prices that can be corroborated with observable market data, as well as quoted prices that were adjusted for security-specific restrictions.
- Level 3: Unobservable inputs to the valuation methodology are significant to the measurement of the fair value of assets or liabilities. Level 3 inputs also include non-binding market consensus prices or non-binding broker quotes that we were unable to corroborate with observable market data.

The Company has elected to measure the convertible promissory notes at fair value on a recurring basis. Changes in fair value are recorded in other income, net, on the consolidated statements of operation and comprehensive loss. Interest accrued on the notes is reflected in interest expense on the consolidated statement of operations.

Cash and cash equivalents

Cash and cash equivalents include unrestricted cash and all highly liquid instruments with original maturities of three months or less at the date of purchase. Cash equivalents consist primarily of amounts invested in money market accounts.

Property and equipment, net

Property and equipment are carried at cost less accumulated depreciation. The costs of additions and betterments are capitalized and expenditures for repairs and maintenance are expensed as incurred. When items of property and equipment are sold or retired, the related costs and accumulated depreciation are removed from the accounts and any gain or loss is included in the consolidated statements of operations and comprehensive loss. Depreciation of property and equipment is provided utilizing the straight-line method over the range of lives used of the respective assets, which is 3 - 10 years.

Leases

The Company determines if an arrangement is a lease at inception. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations and comprehensive loss. The Company recognizes right-of-use (“ROU”) assets and lease liabilities for leases with terms greater than twelve months in the consolidated balance sheets.

ROU assets represent an entity’s right to use an underlying asset during the lease term and lease liabilities represent an entity’s obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. If the lease agreement does not provide an implicit rate in the contract, the lessee uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. For such purposes, the lease term applied may include options to extend or terminate the lease when it is reasonably certain that the Company or a subsidiary will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company has elected to combine lease and non-lease components as a single component. Operating leases are recognized on the consolidated balance sheet as ROU lease assets, current lease liabilities, and non-current lease liabilities. Fixed lease payments are included in the calculation of the lease balances, while variable costs paid for certain operating and pass through costs are excluded.

Intangible assets, net

Intangible assets, consisting primarily of acquired in-process research and development (“IPR&D”) with alternative future use and patents, are stated at acquired cost, less accumulated amortization. Amortization expense is computed using the straight-line method over the estimated useful life of 10 years. The Company’s intangible assets were acquired as a result of the merger closing between Age-X and Serina and were sold in connection with the sale of UniverXome to Juvenescence in December 2024. Amortization expense was \$0.1 million for the year ended December 31, 2024.

Impairment of long-lived assets

The Company assesses the impairment of long-lived assets whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value may not be recoverable. If events or changes in circumstances indicate that

[Table of Contents](#)

the carrying amount of an asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss, equal to the excess of the carrying value of the asset over its fair value, is recorded. There has been no impairment of long-lived assets for the accounting periods presented.

Accounting for warrants

The Company determines the accounting classification of warrants it issues, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the Company to settle the warrants or the underlying shares by paying cash or other assets, or warrants that must or may require settlement by issuing a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, and in order to conclude equity classification, the Company also assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable U.S. GAAP. After all relevant assessments, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants are recorded at fair value upon issuance and subsequently remeasured to fair value each reporting period until settlement with all changes in fair value recorded in the consolidated statements of operations and comprehensive loss. Equity classified warrants are recorded at fair value upon issuance and are not subsequently remeasured. See Note 5, *Related Party Transactions*, Note 6, *Fair Value Measurements*, and Note 7, *Stockholders' (Deficit) Equity* for additional information regarding warrants.

Contingent warrants

Warrants issued in connection with future tranches of debt are initially recorded as Financial Commitment Assets ("FCAs") on the consolidated balance sheet at their fair value upon issuance. The FCAs remain as assets until the related debt tranches are drawn. Upon drawdown, the FCAs are reclassified as a debt discount, reducing the carrying value of the related debt tranche, and are subsequently amortized to interest expense over the term of the respective debt tranche.

The warrants are evaluated to determine their appropriate classification as equity or liability instruments. If the number of shares underlying the warrants is not fixed and varies based on the amount borrowed, the warrants are liability classified and will be remeasured to fair value each reporting period with a charge or credit to the consolidated statements of operations and comprehensive loss. These Contingent warrants and future tranches of debt were subsequently modified in March 2026. Refer to Note 14, *Subsequent Events* for details.

Redeemable convertible preferred stock

Legacy Serina recorded redeemable convertible preferred stock at fair value upon issuance, net of any issuance costs, outside of permanent equity because the shares were redeemable in circumstances not within its control. The redeemable convertible preferred stock was converted into common stock on March 26, 2024 upon consummation of the Merger.

Revenue recognition

The Company receives government grants that reimburse the Company for certain allowable costs for funded projects. Grant revenue is recognized in the consolidated statement of operations on a systematic basis over the period in which the Company recognizes qualified research and development costs that grant is intended to compensate and there is reasonable assurance that the Company will meet the terms and conditions of the grant.

Grant revenues for the years ended December 31, 2025 and 2024 were not material.

Research and development expense

Research and development costs are expensed as they are incurred and primary consist of cost incurred for the development of product candidates and drug discovery efforts, which include personnel costs consisting of salaries, benefits and equity-based compensation expense; expenses incurred under agreements with consultants and contract organizations that conduct research and development activities on the Company's behalf; costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers; laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials; and laboratory supplies and equipment used for internal research and

[Table of Contents](#)

development activities. The Company continually evaluates new product opportunities and engages in intensive research and product development efforts. Research and development expenses include both direct costs tied to a specific contract or grant, and indirect costs. Research and development expenses incurred and reimbursed by grants from third parties or governmental agencies, if any and as applicable, approximate the respective revenues recognized in the consolidated statements of operations and comprehensive loss. Research and development costs may be offset by research grants and research and development refundable tax rebates received by Serina Therapeutics Australia Pty Ltd.

General and administrative expense

General and administrative expenses consist primarily of personnel costs, and other expenses for outside professional services, including legal, recruiting, audit and accounting, insurance and facility related costs not otherwise included in research and development expenses. Personnel costs consist of salaries, benefits and equity-based compensation expense for personnel in executive and other administrative functions.

Income taxes

Income taxes are provided in accordance with ASC Topic 740, which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. ASC 740 guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. Deferred taxes represent the future tax return consequences of those differences, which will either be taxable or deductible when the assets and liabilities are recovered or settled. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the differences are expected to be recovered or settled.

The Company only recognizes tax benefits from an uncertain tax position if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. To date, the Company has not recognized such tax benefits in its consolidated financial statements.

Stock-based compensation expense

The Company provides stock-based payments in the form of stock options and restricted stock awards. For awards only subject to service conditions, the Company uses the straight-line attribution method for recognizing compensation expense over the requisite service period, which is generally the vesting period of the award. Compensation expense is recognized on awards ultimately expected to vest. Forfeitures are recorded when they occur.

The Company estimates the fair value of stock option awards and restricted stock awards on the grant date using a Black-Scholes option pricing model.

Basic and diluted net loss per share attributable to common stockholders

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company's redeemable convertible preferred stock and convertible preferred stock contractually entitle the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company.

Basic loss per share ("EPS") of common stock is computed by dividing net loss available to common stockholders (numerator) by the weighted average number of shares of common stock outstanding (denominator) during the period.

Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method for stock options and warrants and the if-converted method for redeemable convertible preferred stock, convertible preferred stock, and convertible promissory notes. In computing diluted EPS, the average stock price for the period is used

[Table of Contents](#)

to determine the number of shares assumed to be purchased from the exercise of stock options and/or warrants. Diluted EPS excludes all dilutive potential shares if their effect is anti-dilutive.

Segment reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment, Note 13, *Segment Reporting* for additional information.

Recently adopted accounting pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures*, under which entities must consistently categorize and provide greater disaggregation of information in the rate reconciliation. They must also further disaggregate income taxes paid. ASU 2023-09 enhances annual income tax disclosures to address investor requests for more information about the tax risks and opportunities present in an entity's worldwide operations. The Company adopted this standard as of January 1, 2025, and it did not have a material impact on the consolidated financial statements. The Company applied the new disclosure requirements prospectively to the current annual period. See Note 10, *Income Taxes* in the accompanying notes to the consolidated financial statements for further detail.

In March 2024, the FASB issued ASU 2024-02, *Codification Improvements—Amendments to Remove References to the Concepts Statements*. ASU 2024-02 removes various references to the FASB's Concepts Statements from the FASB's Accounting Standards Codification (Codification or GAAP). The Concepts Statements are non-authoritative guidance issued by the FASB that provide the objectives, qualitative characteristics and other concepts that govern the development of accounting principles by the FASB. The ASU indicates that the goal of the amendments is to simplify the Codification and distinguish between nonauthoritative and authoritative guidance (since, unlike the Codification, the concepts statements are nonauthoritative). The Company adopted this standard on January 1, 2025, and it did not have a material impact on the consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* to improve disclosures by providing more detailed information about the types of expenses in commonly presented expense captions. The guidance is effective for annual reporting periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the effect this standard will have on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract*. The ASU adds a scope exception for certain non-exchange traded contracts whose underlyings are based on operations or activities specific to one party and not based on market rates or prices, indexes, or the price or performance of a financial asset or liability of either party. It also clarifies that share-based noncash consideration from a customer in a revenue contract is within the scope of Topic 606 until the entity's right to receive or retain such consideration becomes unconditional under that Topic. The guidance is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those fiscal years, with early adoption permitted on either a prospective or modified retrospective basis. The Company is currently evaluating the effect this standard will have on its consolidated financial statements and related disclosures.

3. Recapitalization

As described in Note 1, Legacy Serina merged with Merger Sub on March 26, 2024 with Legacy Serina surviving the merger as a wholly owned subsidiary of AgeX. The Merger was accounted for as a reverse recapitalization and Legacy Serina was considered the accounting acquirer for financial reporting purposes. This determination was based on the facts that, immediately following the Merger: (i) Legacy Serina stockholders owned a substantial majority of the voting rights; (ii) Legacy Serina designated a majority of the initial members of the board of directors of the combined company; (iii) Legacy Serina's executive management team became the management team of the combined company, and (iv) the combined company intended to primarily focus on developing Legacy Serina's product candidates, and would not continue to develop AgeX's product candidates.

[Table of Contents](#)

At the effective time of the Merger, each outstanding share of Legacy Serina capital stock (after giving effect to the automatic conversion of all shares of Legacy Serina preferred stock into shares of Legacy Serina common stock and excluding any shares held as treasury stock by Legacy Serina or held or owned by AgeX or any subsidiary of AgeX or of Legacy Serina and any dissenting shares) was converted into the right to receive 0.97682654 shares of AgeX common stock which resulted in AgeX issuing an aggregate of 5,913,277 shares of AgeX common stock to the stockholders of Legacy Serina.

Total AgeX shares outstanding prior to Merger	2,500,612
Shares issued to Legacy Serina stockholders	5,913,277
Total shares outstanding	<u>8,413,889</u>

In addition, AgeX assumed the Legacy Serina 2017 Stock Option Plan, and each outstanding and unexercised option to purchase Legacy Serina common stock and each outstanding and unexercised warrant to purchase Legacy Serina capital stock was adjusted with such stock options and warrants henceforth representing the right to purchase a number of shares of Company common stock equal to 0.97682654 multiplied by the number of shares of Legacy Serina common stock previously represented by such options and warrants.

In March 2023, AgeX provided Legacy Serina with bridge financing in the form of a convertible promissory note for the principal amount of \$10.0 million (the "AgeX-Serina Note"). See Note 6, *Fair Value Measurements*, for additional information on the AgeX-Serina Note.

As part of the recapitalization, the Company obtained the assets and liabilities listed below (in thousands):

Cash and cash equivalents	\$	337
Other current assets		174
Intangible assets		576
Accounts payable and accrued expenses		(2,830)
Loan payable to Juvenescence		(8,017)
Net liabilities acquired		<u>(9,760)</u>
Conversion of AgeX-Serina Note		10,721
Total	\$	<u>961</u>

The Company recognized the assets and liabilities acquired and the conversion of the outstanding balance of the AgeX-Serina Note into shares of the Company's common stock upon closing of the Merger, as a net increase in additional paid-in capital within equity for the year ended December 31, 2024.

4. Selected Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets were as follows (in thousands):

	December 31,	
	2025	2024
Financial commitment asset	\$ 1,721	\$ —
Prepaid technology access fee	—	1,333
Prepaid research and development services	585	—
Prepaid insurance	182	192
Other prepaid expenses	227	402
Other current assets	309	77
Total prepaid expenses and other current assets	<u>\$ 3,024</u>	<u>\$ 2,004</u>

[Table of Contents](#)

Property and equipment, net

Property and equipment, net was as follows (in thousands):

	December 31,	
	2025	2024
Equipment	\$ 881	\$ 966
Computers and software	112	136
Total property and equipment, gross	993	1,102
Less: accumulated depreciation and amortization	(528)	(601)
Total property and equipment, net	\$ 465	\$ 501

Depreciation and amortization of property and equipment for each of the years ended December 31, 2025 and 2024 was \$0.1 million.

Accrued liabilities

Accrued liabilities were comprised of the following (in thousands):

	December 31,	
	2025	2024
Research program and services	\$ 231	\$ —
Accrued compensation	812	559
Accrued severance	—	304
Other accrued expenses	164	566
Total accrued expenses	\$ 1,207	\$ 1,429

5. Related Party Transactions

Convertible Notes Agreement and Asset Contribution Agreement

On March 26, 2024, AgeX entered into an Asset Contribution Agreement with UniverXome (the "Asset Contribution Agreement") pursuant to which AgeX transferred to UniverXome all of AgeX's capital stock in Reverse Bio and ReCyte, along with certain patents, patent applications, and other intellectual property, certain biological materials, certain trademarks and service marks, certain equipment, certain inventory, and certain files and records relating to the foregoing, and UniverXome assumed all of the Liabilities (as defined in the Asset Contribution Agreement) in existence as the Effective Time (as defined in the Merger Agreement) other than the Transaction Expenses (as defined in the Merger Agreement) and certain other liabilities. Concurrently with the execution of the Asset Contribution Agreement, AgeX, and its subsidiaries UniverXome, Reverse Bio, and ReCyte (the "Subsidiary Obligor"), entered into an Agreement with Respect to the Convertible Notes (the "Convertible Notes Agreement") with Juvenescence.

Pursuant to the Convertible Notes Agreement, AgeX transferred to UniverXome, and UniverXome assumed, all of AgeX's rights and obligations under the convertible notes issued to Juvenescence in 2022 and 2023 (the "2022 Secured Note" and "2023 Secured Note", respectively) and related Security Agreements. Juvenescence agreed to release AgeX from its obligations under (i) the 2022 Secured Note and the 2023 Secured Note (collectively, the "Convertible Notes"), together with (ii) all agreements evidencing or securing the Convertible Notes, including the related Security Agreements, and UniverXome assumed all of AgeX's obligations under the Convertible Notes and related agreements, including the Security Agreements. As a result, (i) Juvenescence agreed to look solely to UniverXome, and ReCyte and Reverse Bio as guarantors, for any and all obligations, including repayment, under the Convertible Notes, the Security Agreements, and related documents, and (ii) Juvenescence released its security interests in the assets of AgeX and certain subsidiaries, including its security interests in the stock of UniverXome, the stock and assets of Merger Sub, the stock and assets of NeuroAirmid, and certain cGMP embryonic cell lines used to support the NeuroAirmid business, and any security interest that it might have in the stock and assets of Merger Sub and Legacy Serina, while retaining its security interest in the stock and assets of ReCyte and Reverse Bio and in AgeX assets transferred to UniverXome. Juvenescence also agreed to provide

[Table of Contents](#)

the Company with a claims reserve for the purpose of settling and paying the costs associated with certain claims and demands against the Company, which claims reserve will be an additional debt obligation of UniverXome.

The Convertible Notes Agreement amended certain provisions of the 2022 Secured Note and 2023 Secured Note to eliminate (i) the provisions permitting Juvenescence and AgeX to convert outstanding amounts owed into shares of AgeX common stock, and (ii) certain related provisions. Upon the Merger, a portion of the Convertible Notes were converted, leaving a balance of \$10.4 million in loans due to Juvenescence, net of debt issuance, on the consolidated balance sheet. The 2022 Secured Notes also had terms which dictated the issuance of AgeX warrants upon drawdowns of loan funds, however, these were cancelled pursuant to the Merger Agreement and the remaining 2022 Warrants to purchase a total of 129,593 shares of common stock at prices ranging from \$20.75 to \$25.01 remained in effect. As of December 31, 2025, 75,614 warrants expired leaving 53,979 remaining. See Note 7, *Stockholders' (Deficit) Equity*, for details.

Sale of subsidiary to Juvenescence

On December 23, 2024, the Company entered into the Stock Purchase Agreement with Juvenescence, pursuant to which Juvenescence purchased all of the outstanding shares of UniverXome, thereby assuming all Legacy Assets AgeX transferred to UniverXome prior to the Merger. The Legacy Assets included all of AgeX's interests in ReCyte, Reverse Bio along with certain patents, patent applications, and other intellectual property, certain biological materials, certain trademarks and service marks, certain equipment, certain inventory, and certain files and records relating to the foregoing. As consideration for the purchase of UniverXome, Juvenescence assumed the net assets of UniverXome primarily consisting of intangible assets, net, of \$0.5 million, and approximately \$11.3 million of secured debt, consisting of the 2022 Secured Note and 2023 Secured Note owed by UniverXome to Juvenescence in addition to a nominal cash payment. The debt assumed by Juvenescence was secured by substantially all of the assets of UniverXome. As a result of the sale, the Company derecognized all assets and liabilities of UniverXome with a corresponding increase to additional paid-in capital from Juvenescence calculated as the difference between the carrying amount of the extinguished debt and the fair value of the reacquisition price of the debt. For the year ended December 31, 2024, the Company recognized a \$10.9 million capital contribution on the consolidated statement of redeemable convertible preferred stock and stockholders' (deficit) equity.

Series A Convertible Preferred Stock

On April 8, 2025, the Company entered into a securities purchase agreement with related parties for a private placement of 965,250 shares of Series A Convertible Preferred Stock, par value \$0.0001 (the "Series A Preferred Stock"), at \$5.18 per share for net proceeds of \$4.9 million. See Note 7, *Stockholders' (Deficit) Equity*.

2025 Convertible Note and warrants

On September 9, 2025, the Company entered into an unsecured convertible note (the "2025 Convertible Note") with a member of the Company's Board of Directors, making available to the Company an aggregate principal amount of up to \$20 million.

Under the 2025 Convertible Note, borrowings may be drawn at the discretion of the Company in five tranches tied to certain clinical and operational milestones, provided if at the time the Company achieves a milestone, the Company does not have sufficient cash available to cover projected costs and expenses to achieve the next milestone, then the Company will be required to draw such deficiency. The five tranches correspond to the five following milestones: (i) up to \$5 million on or before September 30, 2025; (ii) up to \$2.5 million on or after December 15, 2025 upon enrollment of the first patient in the Company's SER-252-1b registrational clinical study; (iii) up to \$2.5 million upon enrollment of the second patient in the study; (iv) up to \$5 million on or after March 15, 2026, upon dosing of the last patient in Cohort 1 of the study; and (v) up to \$5 million on or after April 30, 2026, upon dosing of the first patient in Cohort 2 of the study ("Milestone 5"). The 2025 Convertible Note was subsequently modified in March 2026. Refer to Note 14, *Subsequent Events* for details.

The funding tranches of the 2025 Convertible Note are subject to the accomplishment of certain SER-252-1b registrational clinical study accomplishments. On November 3, 2025, the Company announced that it received a notice from the FDA placing a clinical hold on the Company's Investigational New Drug ("IND") application for SER-252, the Company's lead development program for advanced Parkinson's disease. The FDA has requested additional information related to a commonly used excipient in the formulation of SER-252. The FDA's feedback did not relate to the active drug substance or its proposed mechanism of action. In January 2026, the Company announced that it had received FDA clearance of the IND application for its lead product, SER-252, for the treatment of advanced Parkinson's disease. In February 2026, the Company enrolled and dosed its first patient in its Phase 1b clinical trial for SER-252.

[Table of Contents](#)

Borrowings under the 2025 Convertible Note bear interest at an annual rate of 10%, initially payable in cash on the first anniversary of the initial funding and on a quarterly basis after. The 2025 Convertible Note contains customary events of default, including an additional 2% of default interest following an event of default, and has a maturity date of five years after the initial funding date. The Company can prepay the 2025 Convertible Note at any time with no penalty. The Company is required to repay all obligations outstanding under the 2025 Convertible Note in cash in the event of certain liquidity events or a change of control of the Company, all as defined in the 2025 Convertible Note.

The 2025 Convertible Note is convertible, at the option of the holder, into shares of the Company's common stock, at any time until the maturity date at a conversion price of \$5.18 per share. The conversion price is subject to standard adjustments in the event of any stock split, stock dividend, stock combination, recapitalization, or other similar transaction.

Borrowings under the 2025 Convertible Note constitute senior unsecured obligations of the Company and rank senior in right of payment to all indebtedness of the Company expressly subordinated to the 2025 Convertible Note, and *pari passu* in right of payment with all other unsecured indebtedness of the Company. The Company may incur additional indebtedness that is junior to the 2025 Convertible Note without restriction, but may not incur additional indebtedness that is senior or *pari passu* in right of payment to the 2025 Convertible Note without the prior written consent of the holder.

Under the 2025 Convertible Note, the Company also agreed to issue warrants ("Contingent Warrants") for the purchase of shares of the Company's Common Stock on each funding date in an amount equal to 100% of the number of shares issuable upon conversion of the funds. See Note 7, *Stockholders' (Deficit) Equity*, for terms regarding these warrants.

While the Contingent Warrants are not legally issued until the Company draws down on the associated tranches of the 2025 Convertible Note, they are considered to be issued for accounting purposes. As no amounts were drawn as of the effective date of the 2025 Convertible Note agreement, the Contingent Warrants were recorded as Financial Commitment Assets ("FCAs"), corresponding to each of the five 2025 Convertible Note tranches, at the initial fair value of the Contingent Warrants of \$3.7 million, in prepaid expenses and other current assets in the consolidated balance sheet. The Company determined that the Contingent Warrants were liability classified as the number of shares underlying the warrants was variable (see Note 7, *Stockholders' (Deficit) Equity*).

In September 2025, the Company drew down the first tranche of \$5.0 million under the 2025 Convertible Note ("First Tranche"), incurring \$0.1 million in transaction costs which were accounted for as a debt discount. The Company also reclassified a pro rata portion of the FCA associated with the First Tranche, recorded at the initial warrant fair value of \$2.0 million, as a debt discount resulting in the net carrying value of the Convertible Note of \$2.9 million and issued 965,251 shares underlying the First Tranche Contingent Warrants.

The Company determined that the First Tranche includes a compound embedded derivative related to mandatory redemption features in the event of certain liquidity events or change of control of the Company and contingent interest upon an event of default feature. The fair value of the compound embedded derivative is not material and has not been separately recognized on the consolidated balance sheet.

6. Fair Value Measurements

Warrant Liabilities

The Company classifies the Merger Warrants and Contingent Warrants (as defined in Note 5, *Related Party* and Note 7, *Stockholders' (Deficit) Equity*) as liabilities. At the end of each reporting period, changes in fair value during the period are recognized as a component of other income (expense), net within the consolidated statements of operations and comprehensive loss. The change in fair value of these warrant liabilities recognized during the during the years ended December 31, 2025 and 2024 was a \$4.3 million gain and a \$13.2 million gain, respectively. The Company will continue adjusting the warrant liability for changes in fair value until the earlier of a) the exercise or expiration of the warrants or b) when the conditions for equity classification are met, at which time the warrant liabilities will be derecognized. In July 2025, the remaining unexercised Post-Merger Warrants and the corresponding Incentive warrants expired, resulting in a gain of \$0.7 million. In September 2025, in connection with the First Tranche drawdown of the 2025 Convertible Note, the Contingent Warrant related to the First Tranche met equity classification criteria and was remeasured at its estimated fair value of \$2.0 million and reclassified to additional paid-in capital. (See Note 7, *Stockholders' (Deficit) Equity*).

The following is a reconciliation of the beginning and ending balances of warrant liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the years ended December 31, 2025 and 2024 (in thousands):

[Table of Contents](#)

	Merger Warrants	Contingent Warrants
Balance as of December 31, 2023	\$ —	\$ —
Fair value at inception of Post-Merger Warrants	18,501	—
Exercise	(1,372)	—
Derecognition of Incentive Warrants	(1,798)	—
Initial recognition of fair value of Replacement Incentive Warrants	1,407	—
Change in fair value	(13,156)	—
Balance as of December 31, 2024	\$ 3,582	\$ —
Fair value at inception	—	3,747
Change in fair value	(2,575)	(1,688)
Expiration	(724)	—
Reclassification to equity	—	(1,971)
Balance as of December 31, 2025	\$ 283	\$ 88

The Company estimates the fair value of warrants using the Black-Scholes-Merton option pricing model with the following assumptions:

	Year ended December 31,	
	2025	2024
Expected volatility	65.1% - 102.2%	99.2% - 125.9%
Expected term (in years)	0.1 – 3.0	0.6 - 3.2
Risk-free interest rate	3.5% - 4.4%	4.1% - 4.3%
Expected dividend yield	0.00%	0.00%

Expected volatility is estimated using the historical volatilities of comparable publicly traded companies over a period equal to the expected term of the warrants as the Company does not have sufficient trading history. The Company estimates the expected term using time to expiration of the warrant. The risk-free interest rate is the yield on a U.S. Treasury zero-coupon issue with a remaining term equal to or approximating the expected term of the warrant.

Convertible Promissory Notes

AgeX-Serina Note

On March 15, 2023, Legacy Serina issued the AgeX-Serina Note in the amount of \$10.0 million to AgeX. The AgeX-Serina Note bore interest at 7% per annum and was scheduled to mature on March 15, 2026. Legacy Serina borrowed the \$10.0 million pursuant to the AgeX-Serina Note to provide for general working capital needs.

Legacy Serina elected to initially and subsequently measure the AgeX-Serina Note in its entirety at fair value, with the fair value inception date adjustment as well as all subsequent changes in fair value recognized in the consolidated statements of operations and comprehensive loss.

On March 15, 2023, the fair value of the \$10.0 million principal amount under the AgeX-Serina Note was evaluated and an adjustment to reduce the fair value of the principal balance to \$7.8 million was recorded at that time. On the date of the Merger, the AgeX-Serina Note was remeasured to its fair value of \$10.7 million as it converted into equity upon the Merger. See Note 3, *Recapitalization* for details. The change in fair value recognized during the year ended 2024 was a \$7.0 million loss.

7. Stockholders' (Deficit) Equity

Common Stock

The holders of common stock are entitled to one vote for each share of common stock which is outstanding on all matters on which stockholders are entitled to vote generally. The holders of shares of common stock do not have cumulative voting rights. Except as otherwise required by law, holders of common stock are not be entitled to vote on any amendment to our Amended and Restated Certificate of Incorporation that relates solely to the terms, number of shares, powers, designations, preferences or relative, participating, optional or other special rights, or to qualifications, limitations or restrictions thereof, of one or more outstanding series of preferred stock if the holders of such affected series are entitled to vote thereon pursuant to our Amended and Restated Certificate of Incorporation or pursuant to the Delaware General Corporation Law. Holders of shares of our common stock will not have any dividend, liquidation, preemptive, subscription or conversion rights, and there will not be any redemption or sinking fund provisions applicable to our common stock.

In March 2024, the Company amended and restated its certificate of incorporation to increase the authorized shares of common stock to consist of 40,000,000 shares of common stock, par value \$0.0001 per share, and 5,000,000 shares of preferred stock, par value \$0.0001 per share.

As of December 31, 2025 and 2024, the Company had reserved common stock on an as-converted basis for future issuance as follows (in thousands):

	Year ended December 31,	
	2025	2024
Common stock warrants issued and outstanding	2,973	1,997
Common stock options issued and outstanding under the Plans	3,157	3,221
Remaining shares available for issuance under the Plan	1,746	1,977
Common stock for Series A Convertible Preferred Stock	965	—
Total reserved common stock	8,841	7,195

Series A Convertible Preferred Stock

On April 8, 2025, the Company entered into a securities purchase agreement for a private placement of 965,250 shares of Series A Convertible Preferred Stock, par value \$0.0001 (the "Series A Preferred Stock"), at \$5.18 per share for net proceeds of \$4.9 million. The Series A Preferred Stock earns cumulative dividends at a rate of 8% per annum that are declared annually beginning on March 31, 2026, and paid in shares of the Company's common stock ("PIK Shares"). As of December 31, 2025, 56,645 dividend shares have been accrued but not declared. The Series A Preferred Stock ranks pari passu with parity stock and senior to junior stock and other indebtedness, with automatic and optional conversion rights. The Series A Preferred Stock is not redeemable.

Per each whole share of Series A Preferred Stock, the holders of Series A Preferred Stock will be entitled to cast the number of votes equal to the number of shares of the Company's common stock into which such holder's Series A Preferred Stock would be convertible into on the record date for the vote or consent of stockholders. The holders of Series A Preferred Stock will vote with the holders of the Company's common stock as a single class and on an as-converted basis, except as provided by law.

The Series A Preferred Stock is convertible, at the holder's option, into the number of shares of the Company's common stock equal to the sum of (i) the quotient of the issuance price divided by the conversion price (initially set at \$5.18) and (ii) any PIK Shares accrued but not yet issued with respect to the shares of Series A Preferred Stock being converted, subject to certain beneficial ownership limitations that require stockholder approval for conversion. All shares of Series A Preferred Stock will automatically convert into shares of the Company's common stock if (i) the volume weighted average price per share of common stock is greater than two times the then effective conversion price for ten trading days within any twenty consecutive trading days and (ii) upon the Company completing an underwritten offering or private placement of the Company's common stock resulting in gross cash proceeds to the Company of at least \$20 million.

In the event of a liquidation, dissolution, or winding up of the Company, holders of Series A Preferred Stock are entitled to receive payment based on the greater of issuance price or the per share consideration paid to common stockholders in the liquidation as if the Series A Preferred Stock had been converted into common stock prior to the liquidation event. After payment of the full liquidation preference of Series A Preferred Stock, distributions by the Company shall be distributed with equal priority among holders of the Series A Preferred Stock and common stock, with Series A Preferred Stock being

[Table of Contents](#)

treated on an as-converted basis, including payment for accrued but unpaid dividends. As of December 31, 2025 the liquidation preference was \$5 million.

Merger Warrants

On March 19, 2024, the Company issued to each holder of AgeX common stock as of the dividend record date, March 18, 2024, three warrants (“Post-Merger Warrants”) for each five shares of AgeX common stock held by such stockholder. Prior to their expiration on July 31, 2025, each Post-Merger Warrant was exercisable for one “Unit” at a price equal to \$13.20 per Unit. Each Unit consisted of (i) one share of the Company's common stock and (ii) one warrant (“Incentive Warrant”). Each Incentive Warrant is exercisable for one share of the Company's common stock at an exercise price of \$18.00 per warrant and will expire four-years after the closing date of the Merger. During the year ended December 31, 2025, 65 Post-Merger Warrants were exercised. Upon the exercise, the holders received 65 shares of the Company's common stock, and were issued 65 Incentive Warrants to purchase an additional 65 shares of the Company's common stock with an exercise price of \$18.00 per share expiring on March 26, 2028. In July 2025, 366,626 Post-Merger Warrants and the corresponding Incentive warrants expired, resulting in a gain on warrants expiration of \$0.7 million. As of December 31, 2025, there were no Post-Merger Warrants remaining and 377,930 Incentive Warrants issued and outstanding. The Company classified the Post-Merger Warrants and the Incentive Warrants as liabilities. See Note 6, *Fair Value Measurements*, regarding accounting for warrant liabilities.

Concurrently with the execution of the Merger Agreement, AgeX, Legacy Serina, and Juvenescence entered into a Side Letter, which became effective immediately prior to the closing of the Merger. The Side Letter provided, among other things, that Juvenescence would exercise all Post-Merger Warrants it holds to provide the Company an additional \$15.0 million in capital according to the following schedule: (x) at least one-third on or before May 31, 2024, (y) at least one-third on or before November 30, 2024, and (z) at least one-third on or before June 30, 2025. Juvenescence received 1,133,593 Post-Merger Warrants. On June 6, 2024, Juvenescence exercised Post-Merger Warrants to purchase 377,865 shares of the Company's common stock at an exercise price of \$13.20 per share, for a total purchase price of \$5.0 million. In addition to the shares of the Company's common stock, upon exercise of the Post-Merger Warrants, Juvenescence also received Incentive Warrants to purchase 377,865 shares of the Company's common stock with an exercise price of \$18.00 per share that expire on March 26, 2028.

Replacement Incentive Warrants

On November 26, 2024, the Company entered into the agreement with Juvenescence (the "Agreement") whereby the Company agreed to issue 1,000,000 shares of its common stock at \$10.00 per share, for an aggregate amount of \$10 million in two equal tranches and to surrender to the Company its outstanding Post-Merger Warrants for the purchase of 755,728 shares of its common stock, including all underlying Incentive Warrants issuable upon exercise thereof. In connection with Agreement, the Company issued to Juvenescence warrants to purchase 755,728 shares of common stock at an exercise price of \$18.00 per share (the “Replacement Incentive Warrants” and, together with the Post-Merger Warrants and the Incentive Warrants, collectively, the “Merger Warrants”). The Replacement Incentive Warrants expire on March 26, 2028. As a result of the transaction, the Company derecognized warrant liabilities of \$1.8 million associated with the surrendered and cancelled Post-Merger and Incentive Warrants and recorded the initial warrant liabilities of \$1.4 million associated with the Replacement Incentive Warrants in the consolidated balance sheet as of December 31, 2024.

The closing on the first tranche occurred on November 27, 2024 and the Company issued 500,000 shares of its common stock to Juvenescence for \$5.0 million. Juvenescence purchased the second tranche of 500,000 shares of its common stock and receive corresponding Replacement Incentive Warrants for \$5.0 million on January 31, 2025.

As of December 31, 2025, Juvenescence held 377,865 Incentive Warrants and 755,728 Replacement Incentive Warrants. The Company classifies the Replacement Incentive Warrants as liabilities. See Note 6, *Fair Value Measurements*, regarding accounting for warrant liabilities.

Contingent Warrants

On September 9, 2025, in connection with the 2025 Convertible Note, the Company agreed to issue to the lender the Contingent Warrants exercisable into an aggregate of up to 3,861,004 shares of the Company's common stock. The number of shares is determined based on 100% of the number of shares issuable upon conversion of respective tranche drawn down under the 2025 Convertible Note. The Contingent Warrants have an exercise price equal to \$5.44 per share and expire on the earlier of sixty days following the achievement of Milestone 5 or September 30, 2026, unless stockholder approval has

[Table of Contents](#)

not been obtained. See Note 5, *Related Party Transactions*, for a discussion of the impact of recent FDA communication on the clinical study and achievement of Milestones.

As the number of shares underlying each Contingent Warrant is not fixed and varies depending on the amount drawn under each tranche of the 2025 Convertible Note, the Contingent Warrants did not meet equity classification criteria and are recorded as liabilities. The warrant liability is remeasured to fair value each reporting period until settlement or until equity classification criteria are met. See Note 6, *Fair Value Measurements*.

In September 2025, upon the Company's draw down of the First Tranche of the 2025 Convertible Note, the number of shares underlying the First Tranche Contingent Warrants became fixed at 965,251 shares and equity classification criteria were met. Therefore, the Company remeasured the warrant liability related to the first tranche Contingent Warrants to the fair value of \$2.0 million, and reclassified the first tranche Contingent Warrants from liabilities to additional paid in capital.

Former AgeX Warrants

As of December 31, 2025, there are 129,593 warrants issued and 53,979 outstanding with exercise prices ranging from \$21.93 to \$25.85 and expiration dates ranging from January 24, 2026 to April 3, 2026. During the year ended December 31, 2025, 75,614 Former AgeX warrants expired. These warrants were issued in connection with drawdowns of loan funds by AgeX from Juvenescence under the 2022 Secured Note and were equity classified. On March 26, 2024, as per the terms of the Side Letter executed concurrently with the Merger Agreement on August 29, 2023, all "out of the money" AgeX warrants were canceled. The number of shares of common stock issuable upon exercise of the remaining "in the money warrants" and the exercise prices of those warrants were adjusted for the reverse stock split ratio of 1 for 35.17.

At-the-Market Offerings

On April 25, 2025, the Company entered into a sales agreement (the "Sales Agreement") with JonesTrading Institutional Services LLC (the "Sales Agent"), with respect to an ATM program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to \$13.3 million through the Sales Agent. The Company will pay the Sales Agent a commission up to 3.0% of the gross sales proceeds of any shares sold under the Sales Agreement. As of December 31, 2025, the Company has sold 0.5 million shares of its common stock, resulting in gross proceeds of \$2.8 million. Thus far in 2026, the Company sold 3.0 million shares of common stock at an average gross price of \$3.36, resulting in additional gross proceeds of \$10.0 million.

8. Stock-Based Awards

Equity Incentive Plan Awards

Serina 2024 Inducement Equity Plan

On August 15, 2024, the Company's Board of Directors adopted the 2024 Inducement Equity Plan, (the "2024 Inducement Plan"). Under the 2024 Inducement Plan, the Company has reserved 1,000,000 shares of its common stock for the grant to new employees or non-employee directors of stock options, stock appreciation rights ("SARs"), sale of restricted stock units ("RSUs"), or other securities as approved by its Board of Directors or the Compensation Committee. As of December 31, 2025, 877,750 stock options remain available for issuance under the 2024 Inducement Equity Plan.

Serina 2024 Equity Incentive Plan

On March 27, 2024, the Company's Board of Directors adopted the 2024 Equity Incentive Plan, (the "2024 Incentive Plan"). Under the 2024 Incentive Plan, the Company has reserved 2,675,000 shares of its common stock for the grant to employees, directors, and consultants of stock options, SARs, RSUs, or other securities as approved by its Board of Directors or the Compensation Committee. As of December 31, 2025, 868,629 shares remain available for issuance under the 2024 Equity Incentive Plan.

Serina 2017 Stock Option Plan

In 2017, the Legacy Serina's Board of Directors adopted the Serina Therapeutics, Inc. 2017 Stock Option Plan (the "2017 Option Plan") that provides for the granting of stock options to employees. Pursuant to the Merger Agreement, the Company assumed the outstanding stock options granted by Legacy Serina under the 2017 Option Plan. Pursuant to the Merger Agreement, no additional options shall be granted under the 2017 Option Plan.

Serina 2017 Equity Incentive Plan

Under the Serina 2017 Equity Incentive Plan, as amended (the “2017 Incentive Plan” and formerly the AgeX 2017 Equity Incentive Plan), the Company has reserved 241,683 shares of common stock for the grant of stock options or the sale of Restricted Stock or for the settlement of RSUs. Pursuant to the Merger Agreement no additional options shall be granted under the 2017 Stock Option Plan.

A summary of Serina stock option activity under all plans and related information was as follows (in thousands, except weighted average exercise price):

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price (per share)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2024	3,221	\$ 4.81	7.7	\$ 7,530
Granted	250	\$ 4.53		
Exercised	(260)	\$ 0.06		\$ 1,321
Cancelled/Forfeited	(54)	\$ 5.00		
Balance at December 31, 2025	<u>3,157</u>	\$ 5.18	7.0	\$ 2,282
Options exercisable at December 31, 2025	<u>1,862</u>	\$ 3.31	5.9	\$ 2,282

A summary of Serina RSU activity was as follows (in thousands, except weighted average exercise price):

	Restricted Stock Units	
	Number of Restricted Stock Units	Weighted-Average Exercise Price (per share)
Balance at December 31, 2024	—	\$ —
Awards granted	5	\$ 5.75
Awards vested	(5)	\$ 5.75
Awards cancelled	—	\$ —
Balance at December 31, 2025	<u>—</u>	\$ —

Stock-based Compensation Expense

During the year ended December 31, 2025, Company granted stock options to purchase 250,250 shares of common stock to certain employees, the Board and consultants under the 2024 Equity Incentive Plan and 2024 Inducement Equity Plan, with a weighted average grant date fair value of \$3.64 per share. The Company also granted 5,000 RSUs under the 2024 Equity Incentive Plan with a weighed average grant date fair value of \$5.75 per share during the year ended December 31, 2025. The aggregate intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was \$1.3 million and \$1.8 million, respectively. Total unrecognized compensation cost related to unvested stock option grants of \$7.6 million as of December 31, 2025 is expected to be 2.3 years.

[Table of Contents](#)

Stock-based compensation expense has been allocated to operating expenses as follows (in thousands):

	Year ended December 31,	
	2025	2024
Research and development	\$ 858	\$ 551
General and administrative	2,935	2,044
Total stock-based compensation expense	\$ 3,793	\$ 2,595

The fair value of each option award is estimated on the date of grant using a Black-Scholes option pricing model applying the weighted-average assumptions including the market price of the underlying common stock, expected option life, risk-free interest rates, volatility, and dividend yield. The assumptions that were used to calculate the grant date fair value of employee and non-employee stock option grants were as follows:

	Year ended December 31,	
	2025	2024
Expected life (in years)	5.0 - 6.1	5.0 - 6.1
Volatility	97.0% - 111.7%	112.7% - 118.3%
Risk-free interest rates	3.7% - 4.7%	3.5% - 4.7%
Dividend yield	—	—

Each of these inputs is subjective and generally requires significant judgment.

Expected Life — The expected life represents the weighted-average period that the Company's stock-based awards are expected to remain outstanding and is determined using the "simplified method", whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Volatility — The volatility is estimated using the historical volatilities of comparable publicly traded companies over a period equal to the expected life as the Company does not have sufficient trading history for its common stock price.

Risk-free interest rates — The risk-free interest rate is determined by reference to the U.S. Treasury fixed rate maturities issues similar in duration to the expected life of the award.

Dividend yield — The Company currently has never paid and has no plans to pay any dividends on its common stock. Therefore, the Company has used an expected dividend rate of zero.

The Company does not recognize deferred income taxes for incentive stock option compensation expense and records a tax deduction only when a disqualified disposition has occurred.

9. Profit Sharing Plan

Through its wholly owned subsidiary, Legacy Serina, the Company has established a 401(k) profit sharing plan (the "PSP") for all eligible employees of the Company. The PSP provides for eligible employee contributions subject to certain annual Internal Revenue Code limits. For participants who are age 50 or older during any calendar year, additional employee contributions are allowed under the PSP, subject to Internal Revenue Code limits.

Employer contributions, if any, may include matching contributions and profit sharing contributions, both of which are made on a discretionary basis and are subject to service and employment requirements. Employer matching contributions and employer profit sharing contributions vest based on a graded vesting schedule. The Company made no discretionary employer matching or employer profit sharing contributions for the years ended December 31, 2025 or 2024.

10. Income Taxes

Domestic and international pre-tax income/(loss) consists of the following (in thousands):

[Table of Contents](#)

	Year Ended December 31,	
	2025	2024
United States	\$ (19,271)	\$ (11,207)
International	74	—
Loss before income taxes	<u>\$ (19,197)</u>	<u>\$ (11,207)</u>

For the year ended December 31, 2025, the Company calculated an immaterial tax provision due to foreign operations. For the year ended December 31, 2024, the Company did not record a tax provision or deferred tax benefit.

The Company has historically filed state income tax returns based on the states in which its employee's reside. As a result, the Company has historically gathered the information necessary to apportion revenue, payroll, rent, and property on a state by state basis. The Company will use this information in order to allocate its current year taxable income/loss to each state based on that's state desired apportionment formula. For the years ended December 31, 2025 and 2024, the majority of the state and local income tax effect was attributable to California and Alabama. The Company is not anticipating any significant new state income returns to be filed for 2025. Franchise taxes calculated are classified as an operational expense and not a component of the income tax provision.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts for income tax purposes.

Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss	\$ 29,795	\$ 22,465
Capital loss carryforward	7,020	6,922
Credits	2,966	2,446
Capitalized research costs	1,961	2,471
Stock based compensation - NQSO	1,667	558
Deferred lease liability	105	127
Accruals and reserves	229	221
Amortization and patent costs	432	453
Other	170	8
Gross deferred tax assets	<u>44,345</u>	<u>35,671</u>
Valuation allowance	(44,174)	(35,445)
Total deferred tax assets	<u>171</u>	<u>226</u>
Deferred tax liabilities:		
Fixed assets	(67)	(76)
Lease ROU asset	(104)	(150)
Total deferred tax liabilities	<u>(171)</u>	<u>(226)</u>
Net deferred tax assets:	<u>\$ —</u>	<u>\$ —</u>

Management regularly assesses the ability to realize deferred tax assets recorded based upon the weight of available evidence, including such factors as recent earnings history and expected future taxable income on a jurisdiction by jurisdiction basis. In the event that the Company changes its determination as to the amount of realizable deferred tax assets, the Company will adjust its valuation allowance with a corresponding impact to the provision for income taxes in the period in which such determination is made. The Company's management believes that, based on a number of factors, it is more likely than not, that all or some portion of the deferred tax assets will not be realized; and accordingly, for the

[Table of Contents](#)

year ended December 31, 2025 and 2024, the Company has provided a valuation allowance against the Company's U.S. net deferred tax assets. The net change in the valuation allowance for the year ended December 31, 2025, was an increase of \$8.7 million.

As of December 31, 2025, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately \$106.8 million and \$94.2 million, which will begin to expire in 2027 and 2026, respectively, with \$82.8 million of our federal net operating loss carryforward lasting indefinitely.

As of December 31, 2025, the Company had federal and state research credit carryforwards of approximately \$3.5 million and \$0.4 million, respectively. The federal research credit carryforwards will begin to expire in 2026 while the California research credits carry forward have an indefinite life.

The Internal Revenue Code of 1986, as amended, imposes restrictions on the utilization of net operating losses in the event of an "ownership change" of a corporation. Accordingly, a company's ability to use net operating losses may be limited as prescribed under Internal Revenue Code Section 382 ("IRC Section 382"). Events which may cause limitations in the amount of the net operating losses that the Company may use in any one year include, but are not limited to, a cumulative ownership change of more than 50% over a three-year period. Utilization of the federal and state net operating losses may be subject to substantial annual limitation due to the ownership change limitations provided by the IRC Section 382 and similar state provisions. Accordingly, the Merger may constitute an ownership change that may materially limit the company's use of their NOL carryforwards.

The Company files income tax returns in the U.S. federal and various state with varying statutes of limitations. The Company is generally no longer subject to tax examinations for years prior to December 31, 2020 for federal purposes and for state purposes, except in certain limited circumstances.

Rate Reconciliation

A reconciliation of the provision for income taxes to the amount computed by applying the federal statutory income tax rate of 21% to pretax income after adoption of ASU 2023-09, for the years ended December 31, 2025 and 2024 was as follows (in thousands):

	Year Ended December 31,			
	2025		2024	
Federal tax at statutory rate	\$ (4,025)	21.0 %	\$ (2,340)	21.0 %
State income taxes	(1,309)	6.8 %	(724)	6.5 %
Foreign tax rate differential	3	— %	—	— %
Credits	(520)	2.7 %	(1,109)	10.0 %
Nondeductible items	(64)	0.3 %	858	(7.7)%
Mark-to-Market	—	— %	1,930	(17.3)%
Unrealized warrant liability	(1,387)	7.2 %	(3,618)	32.5 %
Valuation allowance - Federal	5,323	(27.8)%	18,526	(166.3)%
Valuation allowance - State	3,406	(17.8)%	4,078	(36.6)%
Loss on sale of subsidiary	—	— %	(3,497)	31.4 %
Other items	228	(1.2)%	47	(0.4)%
State change in estimates and apportionment	(1,637)	8.5 %	(678)	6.1 %
Acquired NOLs	—	— %	(10,353)	92.9 %
Acquired capital loss	—	— %	(3,120)	28.0 %
Total	\$ 18	(0.10)%	\$ —	— %

Uncertain Tax Positions

The Company has established a reserve against its U.S. research and development credits, with no related accrued interest. The Company does not believe it is reasonably possible that its unrecognized tax benefits will significantly change in the next twelve months.

[Table of Contents](#)

A reconciliation of beginning and ending balances for unrecognized tax benefits is as follows (in thousands):

Balance at December 31, 2024	\$	816
Increase in balance related to tax positions taken during current year		173
Balance at December 31, 2025	\$	<u>989</u>

As of December 31, 2025 and 2024, the balance of the gross unrecognized tax benefits was \$1.0 million and \$0.8 million, respectively, with no interest and penalties for both years. The Company estimates that there will be no material changes in its uncertain tax positions in the next 12 months. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

11. Commitments and Contingencies

Facilities and Equipment Lease Agreements

The Company leases its lab and office facilities in Huntsville, Alabama, for various terms under long-term, non-cancelable operating lease agreements. The leases expire on various dates from January 2028 through October 2028 and provide for renewal periods of two years.

The Company also leased laboratory equipment under a long-term, non-cancelable operating lease which expired in September 2024 and was subsequently replaced by a month-to-month cancellable agreement.

Supplemental cash flow information related to leases is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 187	\$ 214
Operating cash flows from finance leases	\$ —	\$ 2
Financing cash flows from finance leases	\$ —	\$ 35
Right-of-use assets obtained in exchange for lease obligations		
Operating leases	\$ 115	\$ —

Supplemental balance sheet information related to leases was as follows (in thousands other than weighted average remaining lease term and discount rates):

	December 31,	
	2025	2024
Weighted average remaining lease term		
Operating lease	2.2 years	2.5 years
Finance leases	—	0.2 years
Weighted average discount rate		
Operating lease	7.7%	6.7%
Finance leases	—%	6.7%

[Table of Contents](#)

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of December 31, 2025 (in thousands):

	Operating Leases
Year ending December 31, 2026	\$ 204
Year ending December 31, 2027	161
Year ending December 31, 2028	47
Total undiscounted lease payments	412
Less: imputed interest	(35)
Total lease obligations	377
Less: current portion	(181)
Long-term lease obligations	\$ 196

Litigation – General

The Company is subject to various claims and contingencies in the ordinary course of its business, including those related to litigation, business transactions, employee-related matters, and others. When the Company is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, the Company will record a liability for the loss. If the loss is not probable or the amount of the loss cannot be reasonably estimated, the Company discloses the claim if the likelihood of a potential loss is reasonably possible and the amount involved could be material. The Company is not aware of any claims likely to have a material adverse effect on its financial condition or results of operations.

Tax Filings

The Company's tax filings are subject to audit by taxing authorities in jurisdictions where it conducts business. These audits may result in assessments of additional taxes that are subsequently resolved with the authorities or potentially through the courts. Management believes the Company has adequately provided for any ultimate amounts that are likely to result from these audits; however, final assessments, if any, could be significantly different than the amounts recorded in the consolidated financial statements.

Employment Contracts

The Company has entered into employment contracts with certain executive officers. Under the provisions of the contracts, the Company may be required to incur severance obligations for matters relating to changes in control, as defined, and involuntary terminations.

Partnership with Enable

During May 2024, the Company entered into a partnership with Enable Injections, Inc. (“Enable”), a healthcare innovation company developing and manufacturing the enFuse® wearable drug delivery to develop and commercialize SER-252 (POZ-apomorphine) in combination with enFuse for the treatment of Parkinson’s disease. The Company will develop and commercialize SER-252 (POZ-apomorphine) in combination with enFuse™ for the treatment of Parkinson’s disease. The enFuse™ wearable technology from Enable is designed to overcome both IV infusion and other subcutaneous administration method shortcomings through fast, simple, and convenient delivery, benefiting patients, providers, as well as payers, with the ability for at home self-administration. In May 2024, the Company paid \$2.0 million for a technology access fee, amortizing \$1.3 million and \$0.7 million in the years ended December 31, 2025, and 2024, respectively.

Indemnification

In the normal course of business, the Company may provide indemnifications of varying scope under the Company’s agreements with other companies or consultants, typically for the Company’s research and development programs. Pursuant to these agreements, the Company will generally agree to indemnify, hold harmless, and reimburse the indemnified parties for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the Company’s research and development. Indemnification provisions could also cover third-party infringement claims with respect to patent rights, copyrights, or other intellectual property licensed from the Company to third parties. Office and laboratory leases will also generally indemnify the lessor with respect to certain

[Table of Contents](#)

matters that may arise during the term of the lease. The Registration Rights Agreement between Juvenescence and the Company includes indemnification provisions pursuant to which the parties will indemnify each other from certain liabilities in connection with the registration, offer, and sale of securities under a registration statement, including liabilities arising under the Securities Act. The Company has also agreed to provide the AST Indemnity and the ETC Indemnity pursuant to the Letter of Indemnification described in Note 5, *Related Party Transactions*. The term of these indemnification obligations will generally continue in effect after the termination or expiration of the particular license, lease, or agreement to which they relate. The potential future payments the Company could be required to make under these indemnification agreements will generally not be subject to any specified maximum amount. Historically, the Company has not been subject to any claims or demands for indemnification. The Company also maintains various liability insurance policies that limit the Company's financial exposure and in the case of the AST Indemnity and the ETC Indemnity the Company has received a cross-indemnity from Juvenescence against all claims, damages, liabilities or losses arising out of the AST Indemnity and the ETC Indemnity. As a result, the Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements to date.

12. Net Loss Per Common Share

Net loss per common share is calculated in accordance with ASC 260, Earnings Per Share. Basic and diluted net loss per common share attributable to common stockholders is calculated for the periods presented (in thousands), as follows:

	Year Ended December 31,	
	2025	2024
Net loss per common share attributable to common stockholders, basic and diluted		
NUMERATOR		
Net loss	\$ (19,215)	\$ (11,207)
Less: net loss attributable to noncontrolling interest	33	66
Add: Cumulative undeclared Series A preferred stock dividends	(254)	—
Net loss attributable to Serina common stockholders	<u>\$ (19,436)</u>	<u>\$ (11,141)</u>
DENOMINATOR		
Weighted-average shares of common stock outstanding used to calculate basic net loss per common share	<u>10,190</u>	<u>7,359</u>
Net loss per common share attributable to common stockholders, basic and diluted	<u>\$ (1.91)</u>	<u>\$ (1.51)</u>

For the year ended December 31, 2025 and 2024, the Company had a net loss. See the following table for all the potential dilutive instruments that were excluded from the calculation of diluted net loss per share (in thousands):

	December 31,	
	2025	2024
Stock options	3,157	3,221
Warrants	2,973	1,997
Series A convertible preferred stock	1,022	—
Total anti-dilutive securities	<u>7,152</u>	<u>5,218</u>

Note 13 – Segment Reporting

The Company has one reportable segment relating to the research and development of its POZ platform. The segment derived its revenues from Grant revenue.

[Table of Contents](#)

The Company's CODM, its Chief Executive Officer and the senior executive leadership team manage the Company's operations on an integrated basis for the purposes of allocating resources. When evaluating the Company's financial performance, the CODM regularly reviews total revenues and expenses by specific categories to make informed decisions.

The table below is a summary of the segment revenues, including significant segment expenses (in thousands):

	Year Ending December 31,	
	2025	2024
Revenue	\$ 130	\$ 56
Less:		
Research and development		
Project specific ⁽¹⁾	6,234	2,962
Non-Project specific ⁽²⁾	504	475
Compensation ⁽³⁾	5,837	3,462
Infrastructure Management and Facilities	495	363
Depreciation	85	218
General and administrative		
Professional and outside service fees ⁽⁴⁾	4,171	3,341
Compensation ⁽³⁾	6,339	4,468
Infrastructure Management and Facilities	487	339
Merger and Integration related	—	1,476
Total operating expenses	24,152	17,104
Loss from operations	\$ (24,022)	\$ (17,048)

(1) Research and development project specific expenses largely consist of costs incurred to develop the Company's lead product candidate, SER 252 (POZ-apomorphine) as well as expenses incurred to develop other small molecules, RNA-based therapeutics and antibody-based drug conjugates ("ADCs").

(2) Research and development non-project specific expenses mainly consists of laboratory expenses and fees paid to outside services.

(3) Compensation includes employee salary and fringe benefits, stock based compensation and compensation to independent contractors.

(4) General and administrative professional and outside service fees mainly consist of legal, accounting and audit, board, insurance, and SEC filing fees.

14. Subsequent Events

On March 17, 2026, the Company entered into definitive agreements for the private placement of the Company's common stock and pre-funded warrants, led by a member of the Company's Board of Directors, at \$2.25 per share. Each common stock and pre-funded warrant was accompanied by redeemable warrants to purchase a number of shares equal to 50% of the aggregate shares purchased at an exercise price of \$5.00 per share. All warrants expire four years from the date of issuance and are callable by the Company upon the earlier of (i) 30 days following the dosing of the first patient in Cohort 2 of the SER-252 Phase 1b SAD study, or (ii) September 30, 2026, and in each case subject to the Company's share price exceeding \$10.00 per share on the relevant date. Under the terms of the agreements, the initial funding provided for at least \$15.0 million in gross proceeds, with one or more additional closings for aggregate gross proceeds of at least \$5.0 million and up to \$15.0 million to be funded within 20 days after the initial closing, subject to the satisfaction of customary closing conditions. As of March 23, 2026, the Company has received gross proceeds of \$16.0 million. If fully funded and exercised in full, the redeemable warrants could provide additional gross proceeds of up to \$33.3 million. In connection with the closing of the private placement, the Senior Unsecured Convertible Promissory Note previously entered by the Company on September 9, 2025, was amended to remove any further obligations to borrow or loan funds under the note.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our principal executive officer and principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act) as of the end of the period covered by this report. Following this review and evaluation, the principal executive officer and principal financial officer determined that our disclosure controls and procedures were effective as of December 31, 2025.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on financial statements.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting. Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Previously Reported Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual financial statements will not be prevented or detected on a timely basis.

As reported in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2024, we previously reported identification of material weaknesses due to a lack of internal controls, which primarily stemmed from our small workforce and limited resources prior to the Merger. We implemented a remediation plan that included the following:

- We engaged financial operations employees and consultants to assess and establish internal controls
- To strengthen our accounting and finance team, we hired professionals with technical expertise in public company accounting and financial reporting experience.
- In addition to expanding our internal team, we leverage third-party consultants and specialists to provide technical accounting experience and assist with systems implementation.
- We developed standardized templates and implemented enhanced processes and procedures for accounting, financial close and reporting.
- We implemented automation and integration improvements in our financial IT systems, and are actively working on further enhancements to our platforms.

As a result of these actions, we concluded that our material weaknesses were remediated on December 31, 2025, and our internal control over financial reporting was effective as of December 31, 2025.

[Table of Contents](#)

Changes in Internal Control over Financial Reporting

Other than as described above, there was no change in our internal control over financial reporting that occurred during the period covered by this Annual report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness Over Financial Reporting

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable and not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but there can be no assurance such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following exhibits are filed herewith or incorporated by reference:

Exhibit Number	Description of Document	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1†	Agreement and Plan of Merger and Reorganization, dated August 29, 2023, by and among AgeX Therapeutics, Inc., Canaria Transaction Corporation and Serina Therapeutics, Inc.	8-K	001-38519	2.1	8/30/2023
3.1	Amended and Restated Certificate of Incorporation of Serina Therapeutics, Inc.	8-K	001-38519	3.1	4/1/2024
3.2*	Amended and Restated Bylaws of Serina Therapeutics, Inc., as amended for SEC filing purposes only				
3.3	Certificate of Designations, dated April 10, 2025.	8-K	001-38519	3.1	4/14/2025
3.4	Certificate of Correction, dated May 22, 2025.	8-K	001-38519	3.1	5/22/2025
4.1	Form of Warrant included in Warrant Agreement dated February 14, 2022.	8-K	001-38519	4.1	2/15/2022
4.2*	New Form of Warrant Agreement dated January 31, 2025.				
4.3	Form of Warrant Agreement	8-K	001-38519	4.1	9/15/2025
10.1‡	Amendment to AgeX Therapeutics, Inc. 2017 Equity Incentive Plan	8-K	001-38519	10.1	12/12/2022
10.42‡	Form of Indemnification Agreement for Officers and Directors	8-K	001-38519	10.4	4/1/2024
10.3‡	Director Compensation Policy	8-K	001-38519	10.5	4/1/2024
10.4‡	AgeX Therapeutics, Inc. 2017 Equity Incentive Plan.	S-8	333-229432	99.1	1/30/2019
10.5‡	Form of AgeX Therapeutics, Inc. Employee Stock Option Agreement.	S-8	333-229432	99.2	1/30/2019
10.6‡	Form of AgeX Therapeutics, Inc. Non-Employee Director Stock Option Agreement.	S-8	333-229432	99.3	1/30/2019
10.7‡	Form of AgeX Therapeutics, Inc. Restricted Stock Agreement.	S-8	333-229432	99.4	1/30/2019
10.8‡	Form of AgeX Therapeutics, Inc. Restricted Stock Unit Agreement.	S-8	333-229432	99.5	1/30/2019

Table of Contents

10.9‡	Amendment to AgeX Therapeutics, Inc. 2017 Equity Incentive Plan.	S-8	333-261997	99.1	1/4/2022
10.10‡	Serina Therapeutics Inc. 2024 Equity Incentive Plan.	8-K	001-38519	10.7	4/1/2024
10.11‡	Form of Stock Option Agreement	8-K	001-38519	10.8	4/1/2024
10.12‡	Executive Chairman Agreement, dated as of April 12, 2024, by and between Serina Therapeutics, Inc. and Balkrishan "Simba" Gill.	8-K	001-38519	10.1	4/17/2024
10.13‡	Employment Agreement, effective as of September 9, 2024, among Serina Therapeutics, Inc., Serina Therapeutics (AL), Inc. and Steve Ledger.	8-K	001-38519	10.1	9/12/2024
10.14‡	Employment Agreement, dated as of July 15, 2024, by and between Serina Therapeutics, Inc. and Srimi Tenjarla.	10-Q	001-38519	10.2	11/12/2024
10.15‡	Confidential Consulting Agreement, dated as of May 31, 2024, by and between Serina Therapeutics, Inc. and FLG Partners, LLC	10-Q	001-38519	10.3	11/12/2024
10.16	Convertible Note, dated as of September 9, 2025, between Serina Therapeutics, Inc. and Gregory Bailey.	8-K	001-38519	10.1	9/15/2025
16.1	Letter of WithumSmith+Brown, PC to the Securities and Exchange Commission, dated May 3, 2024	8-K	001-38519	16.1	5/3/2024
19.1*	Serina Therapeutics, Inc. Insider Trading Policy	10-K	001-38519	19.1	3/24/2025
21.1*	List of Subsidiaries				
23.1*	Consent of Frazier & Deeter, LLC				
31.1*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer				
31.2*	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer				
32**	Section 1350 Certification				
97.1*	Serina Therapeutics, Inc. Clawback Policy	10-K	001-38519	19.1	3/24/2025
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				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase				

[Table of Contents](#)

101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

Confidential treatment has been granted with respect to portions of this exhibit (indicated by asterisks) and those portions have been separately filed by Lineage Cell Therapeutics, Inc. with the Securities and Exchange Commission.

† Certain schedules and exhibits to this agreement have been omitted in accordance with Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission on request.

‡ Management contract or compensatory plan.

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 on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 25, 2026

SERINA THERAPEUTICS, INC.

By: /s/ Steve Ledger
Steve Ledger
Chief Executive Officer

Signature	Title	Date
<u>/s/ Balkrishan (Simba) Gill</u> Balkrishan (Simba) Gill, Ph.D	Executive Chairman of the Board of Directors	March 25, 2026
<u>/s/ Steve Ledger</u> Steve Ledger	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 25, 2026
<u>/s/ Gregory S. Curhan</u> Gregory S. Curhan	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 25, 2026
<u>/s/ Gregory H. Bailey</u> Gregory H. Bailey, M.D.	Director	March 25, 2026
<u>/s/ Stephen Brannan</u> Stephen Brannan, M.D.	Director	March 25, 2026
<u>/s/ Richard Marshall</u> Richard Marshall, CBE, M.D., Ph.D.	Director	March 25, 2026
<u>/s/ Jay Venkatesan</u> Jay Venkatesan, M.D.	Director	March 25, 2026
<u>/s/ Karen J. Wilson</u> Karen J. Wilson	Director	March 25, 2026

RESTATED FOR SEC FILING PURPOSES ONLY

**AMENDED AND RESTATED
BYLAWS
OF
SERINA THERAPEUTICS, INC.
(A DELAWARE CORPORATION)**

ARTICLE 1

OFFICES

Section 1.1 Registered Office. The registered office of the corporation in the State of Delaware shall be in the City of Dover, County of Kent.

Section 1.2 Other Offices. The corporation shall also have and maintain an office or principal place of business at such place as may be fixed by the Board of Directors, and may also have offices at such other places, both within and without the State of Delaware, as the Board of Directors may from time to time determine or the business of the corporation may require.

ARTICLE 2

CORPORATE SEAL

The Board of Directors may adopt a corporate seal. The corporate seal shall consist of a die bearing the name of the corporation and the inscription, "Corporate Seal-Delaware." Said seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced or otherwise.

ARTICLE 3

STOCKHOLDERS' MEETINGS

Section 3.1 Place of Meetings. Meetings of the stockholders of the corporation may be held at such place, either within or without the State of Delaware, as may be determined from time to time by the Board of Directors, or, if not so designated, then at the principal offices of the corporation required to be maintained pursuant to Section 1.2 of these bylaws ("Bylaws"). The Board of Directors may, in its sole discretion, determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication as provided under the General Corporation Law of the State of Delaware (the "DGCL").

Section 3.2 Annual Meetings.

(a) The annual meeting of the stockholders of the corporation, for the purpose of the election of directors and for such other business as may properly come before it, shall be

held on such date and at such time as may be designated from time to time by the Board of Directors or a duly authorized committee thereof. At an annual meeting, only such business shall be conducted as is a proper matter for stockholder action under the DGCL and as shall have been properly brought before the meeting. Matters shall be properly brought before the annual meeting only as follows: (i) brought before the meeting and specified pursuant to the corporation's notice of meeting (or any supplement thereto) of stockholders; (ii) otherwise brought specifically by or at the direction of the Board of Directors; and (iii) by any stockholder of the corporation who was a stockholder of record as of the time of the giving of the stockholder's notice provided for in Section 3.2(b) below and as of the record date for the meeting who is entitled to vote at the meeting and who complied with the notice procedures set forth in Section 3.2(b) below; provided, that if such matter is proposed on behalf of a beneficial owner, it may only be properly brought before the meeting if such beneficial owner was the beneficial owner of shares of the corporation at the time of the giving of the stockholder's notice provided for in Section 3.2(b) below. Clause (iii) above shall be the exclusive means for a stockholder to make nominations and submit other business (other than matters properly included in the corporation's notice of meeting of stockholders and proxy statement under Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (the "1934 Act")) before an annual meeting of stockholders. The Board of Directors may postpone, reschedule or cancel any annual meeting of stockholders previously called by the Board of Directors.

(b) At an annual meeting of the stockholders, the following procedures shall apply in order for a matter to be properly brought before the meeting by a stockholder.

(i) For nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 3.2(a) of these Bylaws, the stockholder must deliver written notice to the Secretary at the principal executive offices of the corporation on a timely basis as set forth in Section 3.2(b)(iii) and must update and supplement the information contained in such written notice on a timely basis as set forth in Section 3.2(c). Such stockholder's notice shall set forth (or include, as appropriate): (A) as to each nominee such stockholder proposes to nominate at the meeting: (1) the name, age, business address and residence address of such nominee, (2) the principal occupation or employment of such nominee, (3) the class and number of shares of each class of capital stock of the corporation which are owned of record and beneficially by such nominee and list of any pledge of or encumbrances on such shares, (4) the date or dates on which such shares were acquired and the investment intent of such acquisition, (5) a statement whether such nominee, if elected, (x) intends to tender, promptly following such person's failure to receive the required vote for election or re-election at the next meeting at which such person would face election or re-election, a resignation effective upon acceptance of such resignation by the Board of Directors, in accordance with the corporation's corporate governance policies and guidelines related to conflicts of interest and confidentiality, stock ownership and trading policies and guidelines and any other policies and guidelines applicable to directors, and (y) currently intends to serve as a director for the full term for which such person is standing for election, (6) with respect to each nominee for election or re-election to the Board of Directors, a completed and signed questionnaire, representation and agreement required by Section 3.2(e) of these Bylaws,

and (7) such other information concerning such nominee as would be required to be disclosed in a proxy statement soliciting proxies for the election of such nominee as a director in an election contest (even if an election contest is not involved), or that is otherwise required to be disclosed or provided to the corporation pursuant to Section 14 of the 1934 Act and the rules and regulations promulgated thereunder (including such person's written consent to being named in a proxy statement and associated proxy card as a nominee of the stockholder and to serving as a director if elected); and (B) the information required by Section 3.2(b)(iv). The corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the corporation and to determine the independence of such proposed nominee (as such term is used in any applicable stock exchange listing requirements or applicable law) or to determine the eligibility of such proposed nominee to serve on any committee or sub-committee of the Board of Directors under any applicable stock exchange listing requirements or applicable law, or that the Board of Directors determines, in its sole discretion, could be material to a reasonable stockholder's understanding of the background, qualifications, experience, independence, or lack thereof, of such proposed nominee. The number of nominees a stockholder may nominate for election at the annual meeting on its own behalf (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the annual meeting on behalf of the beneficial owner) shall not exceed the number of directors to be elected at such annual meeting.

(ii) For business other than (i) proposals sought to be included in the corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act, or (ii) nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 3.2(a) of these Bylaws, the stockholder must deliver written notice to the Secretary at the principal executive offices of the corporation on a timely basis as set forth in Section 3.2(b)(iii), and must update and supplement such written notice on a timely basis as set forth in Section 3.2(c). Such stockholder's notice shall set forth: (A) as to each matter such stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend these Bylaws, the language of the proposed amendment), the reasons for conducting such business at the meeting, and any material interest (including any anticipated benefit of such business to any Proponent (as defined below) other than solely as a result of its ownership of the corporation's capital stock, that is material to any Proponent individually, or to the Proponents in the aggregate) in such business of any Proponent; and (B) all of the information required by Section 3.2(b)(iv).

(iii) To be timely, the written notice required by Section 3.2(b)(i) or 3.2(b)(ii) must be received by the Secretary at the principal executive offices of the corporation not later than the close of business on the ninetieth (90th) day nor earlier than the close of business on the one hundred twentieth (120th) day prior to the first anniversary of the prior year's annual meeting of stockholders; *provided, however*, that in the event that the date of the annual meeting is advanced more than thirty (30) days prior to, or delayed by more than seventy (70) days after, the anniversary of the preceding year's annual meeting or if no annual meeting

was held in the preceding year, for notice by the stockholder to be timely, such stockholder's written notice must be delivered to the Secretary not earlier than the close of business on the one hundred twentieth (120th) day prior to such annual meeting and not later than the close of business on the ninetieth (90th) day prior to such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made by the corporation, whichever is later. Notwithstanding the foregoing, in no event shall an adjournment or postponement (or the public announcement thereof) of an annual meeting for which notice has been given or with respect to which there has been a public announcement of the date of the meeting commence a new time period for the giving of a stockholder's notice as described above.

(iv) The written notice required by Section 3.2(b)(i) or 3.2(b)(ii) shall also set forth, as of the date of the notice and as to the stockholder, including all control persons, as defined below, of a stockholder that is an entity, giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made, including all control persons of a beneficial owner that is an entity (each, a "Proponent" and collectively, the "Proponents," including any person who is a member of a "group" (as such term is used in Rule 13d-5 promulgated under the 1934 Act) with any other Proponent with respect to the stock of the corporation, including any proposed nominee, and any person Acting in Concert, as defined below, with any Proponent): (A) the name and address of the stockholder giving notice, as they appear on the corporation's books, and of each other Proponent; (B) the class, series and number of shares of the corporation that are owned beneficially (within the meaning of Rule 13d-3 under the 1934 Act) and of record by each Proponent (*provided*, that for purposes of this Section 3.2(b)(iv), such Proponent shall in all events be deemed to beneficially own all shares of any class or series of capital stock of the corporation as to which such Proponent has a right to acquire beneficial ownership at any time in the future); (C) a description of any agreement, arrangement or understanding (whether oral or in writing, and regardless to whether it relates specifically to the corporation) with respect to such nomination or proposal (and/or the voting of shares of any class or series of capital stock of the corporation) between or among any Proponent and any of its affiliates or associates and/or any other persons (including their names), including, in the case of a nominee, including any agreement, arrangement or understanding (whether oral or in writing) relating to any compensation or payments to be paid to any such proposed nominee(s); (D) a representation that the stockholder giving the notice is a holder of record of shares of the corporation entitled to vote at the meeting and that such stockholder (or its qualified representative, as defined below) intends to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice (with respect to a notice under Section 3.2(b)(i)) or to propose the business that is specified in the notice (with respect to a notice under Section 3.2(b)(ii)); (E) a representation that the beneficial owner, if any, on whose behalf the nomination or proposal is made is the beneficial owner of shares of the corporation; (F) a representation as to whether the Proponents or any other participant (as defined in Item 4 of Schedule 14A under the Exchange Act) will engage in a solicitation with respect to such nomination or proposal and, if so, the name of each participant in such solicitation and the amount of the cost of solicitation that has been and will be borne, directly or indirectly, by each participant in such solicitation and a representation whether the stockholder intends or is part of a group that intends (x) to solicit proxies from the required number of the corporation's shares of

capital stock entitled to vote in the election of directors in support of any proposed nominee in accordance with and as required by Rule 14a-19 promulgated under the 1934 Act, (y) to deliver, or make available, a proxy statement and form of proxy to holders of at least the percentage of the corporation's voting shares required to approve or adopt the proposal or elect the nominee and/or (z) to otherwise solicit proxies or votes from stockholders in support of any nominee or any such proposal; (G) a description of all Derivative Transactions (as defined below) by each Proponent during the previous twelve (12) month period, including the date of the transactions and the class, series and number of securities involved in, and the material economic or voting terms of, such Derivative Transactions; (H) a certification that each Proponent has complied with all applicable federal, state and other legal requirements in connection with such Proponent's acquisition of shares of capital stock or other securities of the corporation and/or such Proponent's acts or omissions as a stockholder or beneficial owner of the corporation; and (I) any other information relating to the Proponents required to be disclosed in a proxy statement or other filings made in connection with solicitations of proxies for, as applicable, the proposal and/or for the election of directors in a contested election pursuant to and in accordance with Section 14 of the 1934 Act and the rules and regulations promulgated thereunder (whether or not such Proponent intends to deliver a proxy statement or conduct a proxy solicitation).

For purposes of Sections 3.2 and 3.3, a "Derivative Transaction" means any agreement, arrangement, interest or understanding entered into by, or on behalf or for the benefit of, any Proponent or any of its affiliates or associates, whether record or beneficial:

(i) the value of which is derived in whole or in part from the value of any class or series of shares or other securities of the corporation,

(ii) which otherwise provides any direct or indirect opportunity to gain or share in any gain derived from a change in the value of securities of the corporation,

(iii) the effect or intent of which is to mitigate loss, manage risk or benefit from changes in value or price with respect to any securities of the corporation, or

(iv) which provides the right to vote or increase or decrease the voting power of, such Proponent, or any of its affiliates or associates, directly or indirectly, with respect to any securities of the corporation, which agreement, arrangement, interest or understanding may include, without limitation, any option, warrant, debt position, note, bond, convertible security, swap, stock appreciation right or similar right, short position, profit interest, hedge, right to dividends, voting agreement, performance-related fee or arrangement to borrow or lend shares (whether or not subject to payment, settlement, exercise or conversion in any such class or series), and any proportionate interest of such Proponent in the securities of the corporation held by any general or limited partnership, or any limited liability company, of which such Proponent is, directly or indirectly, a general partner or managing member.

A person shall be deemed to be "Acting in Concert" with another person for purposes of these Bylaws if such person knowingly acts (whether or not pursuant to an express agreement, arrangement or understanding) in concert with, or towards a common goal relating to the management, governance or control of the corporation in parallel with, such other person

where (A) each person is conscious of the other person's conduct or intent and this awareness is an element in their decision-making processes and (B) at least one additional factor suggests that such persons intend to act in concert or in parallel, which such additional factors may include, without limitation, exchanging information (whether publicly or privately), attending meetings, conducting discussions, or making or soliciting invitations to act in concert or in parallel; provided, that a person shall not be deemed to be Acting in Concert with any other person solely as a result of the solicitation or receipt of revocable proxies or consents from such other person in response to a solicitation made pursuant to, and in accordance with, Section 14(a) of the Exchange Act by way of a proxy or consent solicitation statement filed on Schedule 14A. A person Acting in Concert with another person shall be deemed to be Acting in Concert with any third party who is also Acting in Concert with such other person.

For purposes of this Section 3.2, a "control person" of a stockholder that is an entity or a beneficial owner that is an entity includes each individual who is a director, executive officer, general partner, or managing member of such entity or of any other entity that has or shares control of that entity.

(c) A stockholder providing written notice required by Section 3.2(b)(i) or (ii) shall update and supplement such notice in writing, if necessary, so that the information (other than the representations required by Section 3.2(b)(iv)(F)) provided or required to be provided in such notice is true and correct in all material respects as of (i) the record date for the determination of stockholders entitled to notice of the meeting and (ii) the date that is five (5) business days prior to the meeting and, in the event of any adjournment or postponement thereof, five (5) business days prior to any adjournment or postponement thereof; provided, that no such update or supplement shall cure or affect the accuracy (or inaccuracy) of any representations made by any Proponent, any of its affiliates or associates, or a nominee or the validity (or invalidity) of any nomination or proposal that failed to comply with this Section 3.2 or is rendered invalid as a result of any inaccuracy therein. In the case of an update and supplement pursuant to clause (i) of this Section 3.2(c), such update and supplement shall be delivered to the Secretary at the principal executive offices of the corporation not later than five (5) business days after the later of the record date for the determination of stockholders entitled to notice of the meeting or the public announcement of such record date. In the case of an update and supplement pursuant to clause (ii) of this Section 3.2(c), such update and supplement shall be delivered to the Secretary at the principal executive offices of the corporation not later than two (2) business days prior to the date for the meeting, and, in the event of any adjournment or postponement thereof, two (2) business days prior to any adjournment or postponement thereof.

(d) Notwithstanding anything in Section 3.2(b)(iii) to the contrary, in the event that the number of directors is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board of Directors made by the corporation at least ten (10) days before the last day a stockholder may deliver a notice of nomination in accordance with Section 3.2(b)(iii), a stockholder's notice required by this Section 3.2 and which complies with the requirements in Section 3.2(b)(i), other than the timing requirements in Section 3.2(b)(iii), shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be received by the Secretary

at the principal executive offices of the corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the corporation.

(e) To be eligible to be a nominee for election or re-election as a director of the corporation pursuant to a nomination under clause (iii) of Section 3.2(a), such nominee or a person on his or her behalf must deliver (in accordance with the time periods prescribed for delivery of notice under Section 3.2(b)(iii) or 3.2(d), as applicable) to the Secretary at the principal executive offices of the corporation a completed and signed written questionnaire with respect to the background, qualifications, stock ownership and independence of such proposed nominee and the background of any other person or entity on whose behalf the nomination is being made (which questionnaire shall be provided by the Secretary upon written request) and a written representation and agreement (in the form provided by the Secretary upon written request) that such person (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the corporation, will act or vote on any issue or question (a "Voting Commitment") that has not been disclosed to the corporation in the questionnaire or (B) any Voting Commitment that could limit or interfere with such person's ability to comply, if elected as a director of the corporation, with such person's fiduciary duties under applicable law; (ii) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director of the corporation or as a nominee that has not been disclosed to the corporation in the questionnaire; and (iii) in such person's individual capacity and on behalf of any person or entity on whose behalf the nomination is being made, would be in compliance, if elected as a director of the corporation, and will comply with, all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the corporation, and (iv) if elected as a director of the corporation, intends to serve the entire term until the next meeting at which such candidate would face re-election.

(f) A person shall not be eligible for election or re-election as a director unless the person is nominated, in the case of an annual meeting, in accordance with clause (i), (ii), or (iii) of Section 3.2(a), or, in the case of a special meeting, in accordance with clause (c)(ii) of Section 3.3 of these Bylaws. Except as otherwise required by law, the chair of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before an annual or special meeting was made, or proposed, as the case may be, in accordance with the procedures and requirements set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws (including, without limitation, compliance with Rule 14a-19), or the Proponent does not act in accordance with the representations required in this Section 3.2, to declare that such proposal or nomination shall not be presented for stockholder action at the meeting and shall be disregarded, or that such business shall not be transacted, notwithstanding that such proposal or nomination is set forth in the corporation's proxy statement, notice of meeting or other proxy materials and notwithstanding that proxies or votes in respect of such nomination or such business may have been solicited or

received. Notwithstanding anything in these Bylaws to the contrary, unless otherwise required by law, if (i) a stockholder intending to make a nomination at a meeting pursuant to Section 3.2(b)(i) (or Section 3.3(c) with respect to a special meeting) or to propose business at a meeting pursuant to Section 3.2(b)(ii) does not provide the information in the stockholder's notice required under Section 3.2(b)(i) or 3.2(b)(ii), as applicable, and Section 3.2(b)(iv) within the applicable time periods specified in this Section 3.2, or Section 3.3 as applicable, (including any update and supplement required under Section 3.2(c)), (ii) the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to make such nomination or to propose such business (whether pursuant to the requirements of these Bylaws or in accordance with Rule 14a-8 under the 1934 Act), or (iii) the Proponents shall not have acted in accordance with the representations required under Section 3.2(b)(iv)(F), such nomination or proposal shall not be presented for stockholder action at the meeting and shall be disregarded (and any such nominee shall be disqualified), as determined by the chair of the meeting as described above, notwithstanding that proxies in respect of such nominations or such business may have been solicited or received. To be considered a qualified representative of a stockholder for purposes of these Bylaws, a person must be a duly authorized officer, manager or partner of such stockholder or authorized by a writing executed by such stockholder (or a reliable reproduction of the writing) delivered to the corporation prior to the making of such nomination or proposal at such meeting (and in any event not fewer than five (5) business days before the meeting) stating that such person is authorized to act for such stockholder as proxy at the meeting of stockholders. Notwithstanding anything to the contrary in these Bylaws, unless otherwise required by law, if any Proponent (i) provides notice pursuant to Rule 14a-19(b) under the 1934 Act with respect to any proposed nominee and either subsequently (x) fails to comply with the requirements of Rule 14a-19 under the 1934 Act (or fails to timely provide reasonable evidence sufficient to satisfy the corporation that such Proponent has met the requirements of Rule 14a-19(a)(3) under the 1934 Act in accordance with the following sentence) or (y) fails to inform the corporation that they no longer plan to solicit proxies in accordance with the requirements of Rule 14a-19 under the 1934 Act by delivering a written notice to the Secretary at the principal executive offices of the corporation within two (2) business days after the occurrence of such change, then the nomination of each such proposed nominee shall be disregarded (and such nominees shall be disqualified), notwithstanding that the nominee is included as a nominee in the corporation's proxy statement, notice of meeting or other proxy materials for any annual meeting (or any supplement thereto) and notwithstanding that proxies or votes in respect of the election of such proposed nominees may have been received by the corporation (which proxies and votes shall be disregarded). If any Proponent provides notice pursuant to Rule 14a-19(b) under the 1934 Act, such Proponent shall deliver to the corporation, no later than five (5) business days prior to the applicable meeting, reasonable evidence that it has met the requirements of Rule 14a-19(a)(3) under the 1934 Act. Notwithstanding anything to the contrary set forth herein, and for the avoidance of doubt, the nomination of any person whose name is included as a nominee in the corporation's proxy statement, notice of meeting or other proxy materials for any annual meeting (or any supplement thereto) as a result of any notice provided by any Proponent and any of its affiliates or associates pursuant to Rule 14a-19(b) promulgated under the 1934 Act with respect to such proposed nominee and whose nomination is not made by or at the direction of the Board of Directors or any authorized committee thereof shall not be deemed (for purposes of clause (i) of Section 3.2(a) or otherwise) to have been made pursuant to the corporation's notice of meeting

(or any supplement thereto) and any such nominee may only be nominated by a Proponent pursuant to clause (iii) of Section 3.2(a) (and, in the case of a special meeting of stockholders pursuant to and to the extent permitted under Section 3.3(c)).

(g) Notwithstanding the foregoing provisions of this Section 3.2, in order to include information with respect to a stockholder proposal in the proxy statement and form of proxy for a stockholders' meeting, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however*, that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to proposals and/or nominations to be considered pursuant to Section 3.2(a) of these Bylaws.

(h) For purposes of Sections 3.2 and 3.3,

(i) "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act;

(ii) "affiliates" and "associates" shall have the meanings set forth in Rule 405 under the 1933 Act; and

(iii) "close of business" shall mean 5:00 p.m. local time at the principal place of business of the corporation on any calendar day, whether or not the day is a business day.

Section 3.3 Special Meetings.

(a) Except as otherwise required by law and subject to the rights of the holders of any series of Preferred Stock, special meetings of the stockholders of the corporation for any purpose or purposes may be called at any time only by or at the direction of the Board of Directors or the chair of the Board of Directors. The Board of Directors may postpone, reschedule or cancel any special meeting of stockholders.

(b) Stockholders shall not be permitted to propose business to be brought before a special meeting of stockholders and the only matters that may be brought before a special meeting are the matters specified in the notice of meeting given by or at the direction of the person calling the meeting. The Board of Directors shall determine the time and place of such special meeting. Upon determination of the time and place of the meeting, the officer receiving the request shall cause notice to be given to the stockholders entitled to vote, in accordance with the provisions of Section 3.4 of these Bylaws. Nothing contained in this paragraph (b) shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board of Directors may be held.

(c) Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the corporation's notice of meeting (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the corporation who is a stockholder of record at the time of giving notice provided for in these Bylaws who shall be entitled to vote at the meeting and who delivers written notice to the Secretary of the corporation setting forth the information required by Section 3.2(b)(i) and (iv); provided, that if such nominee(s) are proposed on behalf of a beneficial owner, such nominations may only be properly brought before the meeting if such beneficial owner was the beneficial owner of shares of the corporation at the time of the giving of the stockholder's notice set forth in this paragraph. In the event the corporation calls a special meeting of stockholders for the purpose of electing of one or more directors to the Board of Directors, any such stockholder of record may nominate a person or persons (as the case may be), for election to such position(s) as specified in the corporation's notice of meeting, if the stockholder's notice required by this Section 3.3(c) that includes the information required by Section 3.2(b)(i) and (iv) of these Bylaws shall be delivered to the Secretary at the principal executive offices of the corporation not earlier than the close of business on the one hundred twentieth (120th) day prior to such special meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such meeting or the tenth (10th) day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting. The stockholder shall also update and supplement such information as required under Section 3.2(c). In no event shall an adjournment or postponement (or the public announcement thereof) of a special meeting commence a new time period for the giving of a stockholder's notice as described above. The number of nominees a stockholder may nominate for election at the special meeting (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the special meeting on behalf of such beneficial owner) shall not exceed the number of directors to be elected at such special meeting.

(d) Notwithstanding the foregoing provisions of this Section 3.3, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder with respect to matters set forth in this Section 3.3. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however*, that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to nominations for the election to the Board of Directors to be considered pursuant to Section 3.3(c) of these Bylaws.

Section 3.4 Notice of Meetings. Except as otherwise provided by law, notice, given in writing or by electronic transmission in the manner provided by Section 232 of the DGCL, of each meeting of stockholders shall be given not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting, such notice to specify the place, if any, date and hour, in the case of special meetings, the purpose or purposes of the meeting, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at any such meeting. If mailed,

notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. Notice of the time, place, if any, and purpose of any meeting of stockholders may be waived in writing, signed by the person entitled to notice thereof, or by electronic transmission by such person, either before or after such meeting, and will be waived by any stockholder by the stockholder's attendance thereat in person, by remote communication, if applicable, or by proxy, except when the stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given.

Section 3.5 Quorum. At all meetings of stockholders, except where otherwise provided by statute or by the Certificate of Incorporation, or by these Bylaws, the presence, in person, by remote communication, if applicable, or by proxy duly authorized, of the holders of a majority of the voting power of all the then-outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business. In the absence of a quorum, any meeting of stockholders may be adjourned, from time to time, either by the chair of the meeting or by vote of the holders of a majority of the voting power of the shares represented thereat, but no other business shall be transacted at such meeting. The stockholders present at a duly called or convened meeting, at which a quorum is present, may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Except as otherwise provided by statute or by applicable stock exchange rules or the rules of The New York Stock Exchange, or by the Certificate of Incorporation or these Bylaws, the affirmative vote of the majority of shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Where a separate vote by a class or classes or series is required, except where otherwise provided by the statute or by the Certificate of Incorporation or these Bylaws, a majority of the voting power of the then-outstanding shares of such class or classes or series, present in person, by remote communication, if applicable, or represented by proxy duly authorized, shall constitute a quorum entitled to take action with respect to that vote on that matter. Except where otherwise provided by statute or by the Certificate of Incorporation or these Bylaws, the affirmative vote of the majority of the voting power of the shares of such class or classes or series present in person, by remote communication, if applicable, or represented by proxy at the meeting shall be the act of such class or classes or series.

Section 3.6 Adjournment and Notice of Adjourned Meetings. Any meeting of stockholders, whether annual or special, may be adjourned from time to time either by the chair of the meeting or by the vote of a majority of the voting power of the shares casting votes present in person, by remote communication, if applicable, or represented by proxy at the meeting. When a meeting is adjourned to another time or place, if any, (including an adjournment taken to address a technical failure to convene or continue a meeting using remote communication), notice need not be given of the adjourned meeting if the time and place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are (i) announced at the meeting at which the adjournment is taken, (ii) displayed, during the time scheduled for the

meeting, on the same electronic network used to enable stockholders and proxy holders to participate in the meeting by means of remote communication, or (iii) set forth in the notice of meeting given in accordance with Section 3.4. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 3.7 Voting Rights. For the purpose of determining those stockholders entitled to vote at any meeting of the stockholders, except as otherwise provided by law, only persons in whose names shares stand on the stock records of the corporation on the record date, as provided in Section 3.9 of these Bylaws, shall be entitled to vote at any meeting of stockholders. Unless otherwise provided in the corporation's Certificate of Incorporation each stockholder, shall at every meeting of the stockholders, be entitled to one vote for each share of capital stock having voting power held by such stockholder. Every person entitled to vote shall have the right to do so in person, by remote communication, if applicable, or by an agent or agents authorized by a proxy granted in accordance with the DGCL. An agent so appointed need not be a stockholder. No proxy shall be voted or acted upon after three (3) years from its date of creation unless the proxy provides for a longer period. Any stockholder directly or indirectly soliciting proxies from other stockholders must use a proxy card color other than white, which shall be reserved for the exclusive use by the Board of Directors.

Section 3.8 Joint Owners of Stock. If shares or other securities having voting power stand of record in the names of two (2) or more persons, whether fiduciaries, members of a partnership, joint tenants, tenants in common, tenants by the entirety, or otherwise, or if two (2) or more persons have the same fiduciary relationship respecting the same shares, unless the Secretary is given written notice to the contrary and is furnished with a copy of the instrument or order appointing them or creating the relationship wherein it is so provided, their acts with respect to voting shall have the following effect: (a) if only one (1) votes, his act binds all; (b) if more than one (1) votes, the act of the majority so voting binds all; (c) if more than one (1) votes, but the vote is evenly split on any particular matter, each faction may vote the securities in question proportionally, or may apply to the Delaware Court of Chancery for relief as provided in the DGCL, Section 217(b). If the instrument filed with the Secretary shows that any such tenancy is held in unequal interests, a majority or even-split for the purpose of subsection (c) shall be a majority or even-split in interest.

Section 3.9 List of Stockholders. The officer in charge of the stock ledger of the corporation or the transfer agent shall prepare, no later than the tenth day before each meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; provided, however, if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing contained in this section shall require the corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of

any stockholder for any purpose germane to the meeting for a period of 10 days ending on the day before the meeting date: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the principal place of business of the corporation. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. For purposes of this Section 3.9, “stock ledger” means 1 or more records administered by or on behalf of the corporation in which the names of all of the corporation’s stockholders of record, the address and number of shares registered in the name of each such stockholder, and all issuances and transfers of stock of the corporation are recorded in accordance with § 224 of the DGCL. The stock ledger shall be the only evidence as to who are the stockholders entitled by this Section 3.9 to examine the list required by this Section 3.9 or to vote in person or by proxy at any meeting of stockholders.

Section 3.10 No Action Without Meeting. Any action required or permitted to be taken by the stockholders of the corporation must be effected at a duly called annual or special meeting of stockholders and may not be effected by a consent or consents (written, electronic, or otherwise) of such stockholders.

Section 3.11 Organization.

(a) At every meeting of stockholders, the Chair of the Board of Directors, or, if a Chair has not been appointed or is absent, the Chief Executive Officer and President, or, if the Chief Executive Officer and President has not been appointed or is absent, a chair of the meeting chosen by the a majority of the Board of Directors shall act as chair of the meeting. The Secretary, or in his or her absence any person appointed by the chair of the meeting, shall act as secretary of the meeting.

(b) The corporation shall be entitled to make such rules or regulations for the conduct of meetings of stockholders as it shall deem necessary, appropriate or convenient. Subject to such rules and regulations of the Board of Directors, if any, the chair of the meeting shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chair, are necessary, appropriate or convenient for the proper conduct of the meeting, including, without limitation, establishing an agenda or order of business for the meeting, making a determination concerning whether business is properly brought before the meeting, rules and procedures for maintaining order at the meeting and the safety of those present, limitations on participation in such meeting to stockholders of record of the corporation and their duly authorized and constituted proxies and such other persons as the chair shall permit, restrictions on entry to the meeting after the time fixed for the commencement thereof, limitations on the time allotted to questions or comments by participants and regulation of the opening and closing of the polls for balloting on matters which are to be voted on by ballot. The date and time of the opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting. Unless and to the extent determined by the chair of the meeting, meetings of stockholders shall not be required to be held in accordance with rules of parliamentary procedure.

ARTICLE 4

DIRECTORS

Section 4.1 Number and Term of Office.

(a) Except as otherwise provided for or fixed pursuant to the provisions of the Certificate of Incorporation relating to the rights of the holders of any series of Preferred Stock to elect additional directors, the precise number of directors shall be determined from time to time exclusively by resolution adopted by the Board of Directors. Directors need not be stockholders unless so required by the Certificate of Incorporation.

(b) At any meeting of stockholders for the election of one or more directors at which a quorum is present, each such director shall be elected by the affirmative vote of the majority of the votes cast with respect to that director, provided that if the number of nominees at such meeting, determined at any time, including as of the record date for such meeting, exceeds the number of directors to be elected (a “Contested Election”), the directors shall be elected by the vote of a plurality of the shares represented in person or by proxy at any such meeting and entitled to vote on the election of directors. For purposes of this Section, a majority of the votes cast means that the number of shares voted “for” a director must exceed the number of votes cast as “against” for that director. “Abstentions” and “broker non-votes” with respect to that director’s election shall not be counted as votes cast. In an election other than a Contested Election, stockholders will be given the choice to cast votes “for” or “against” the election of directors or to “abstain” from such vote and shall not have the ability to cast any other vote with respect to such election of directors. In a Contested Election, stockholders will be given the choice to cast “for” or “withhold” votes for the election of directors and shall not have the ability to cast any other vote with respect to such election of directors. If a director then serving on the Board of Directors does not receive the necessary votes, the director shall offer to tender his or her resignation to the Board. The Nominating and Corporate Governance Committee or other committee that may be designated by the Board will make a recommendation to the Board on whether to accept or reject the resignation, or whether other action should be taken. The Board will act on such committee’s recommendation and publicly disclose its decision and the rationale within 90 days from the date of the certification of the election results. In making their decision, the Committee and the Board will evaluate the best interests of the Company and its stockholders and shall consider all factors and information deemed relevant. The director who tenders his or her resignation will not participate in the Committee’s recommendation or the Board’s decision.

Section 4.2 Nomination of Director Candidates. Nominations for the election of Directors at the annual meeting, by or at the direction of the Board of Directors, may be made by any nominating committee or person appointed by the Board of Directors. Nominations may also be made by any stockholder of record of the corporation entitled to vote for the election of directors at the annual meeting who complies with the notice procedures set forth in Section 3.2 hereof. Nominations for the election of directors at a special meeting of stockholders shall be made pursuant to the procedures of Section 3.3 hereof.

Section 4.3 Powers. The powers of the corporation shall be exercised, its business conducted and its property controlled by or under the direction of the Board of Directors, except as may be otherwise provided by statute or by the Certificate of Incorporation.

Section 4.4 Classes of Directors. Subject to the next sentence hereof and to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the Board of Directors is and shall remain divided into three classes (Class I, Class II, and Class III), with the directors in each class serving for a term expiring at the third annual meeting of stockholders held after their election. The initial terms of the members of the Board of Directors shall be as follows: the initial Class I Directors shall serve for a term expiring at the second annual meeting of stockholders of the corporation following the effective date of the First Amended and Restated Certificate of Incorporation of the corporation; the initial Class II Directors shall serve for a term expiring at the third annual meeting of stockholders following the effective date of the First Amended and Restated Certificate of Incorporation of the corporation; and the initial Class III Directors shall serve for a term expiring at the fourth annual meeting of stockholders following the effective date of the First Amended and Restated Certificate of Incorporation of the corporation. Each director in each class shall hold office until his or her successor is duly elected and qualified. At each annual meeting of stockholders beginning with the first annual meeting of stockholders following the effective date of the First Amended and Restated Certificate of Incorporation, the successors of the class of directors whose term expires at that annual meeting shall be elected to hold office for a term expiring at the annual meeting of stockholders to be held in the third year following the year of their election, with each director in each such class to hold office until his or her successor is duly elected and qualified. Notwithstanding the foregoing provisions of this Section 4.4, each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Section 4.5 Vacancies. Subject to the rights granted to the holders of any one or more series of Preferred Stock then outstanding, any newly-created directorship on the Board of Directors that results from an increase in the number of directors and any vacancy occurring on the Board of Directors (whether by death, resignation, retirement, disqualification, removal or other cause) shall be filled only by a majority of the directors then in office, even if less than a quorum, or by a sole remaining director (and not by the stockholders). Any director elected to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall be elected and qualified, or until his or her earlier death, resignation, retirement, disqualification or removal.

Section 4.6 Resignation. Any director may resign at any time by delivering his or her notice in writing or by electronic transmission to the Secretary, such resignation to specify whether it will be effective at a particular time, upon receipt by the Secretary or at the pleasure of the Board of Directors. If no such specification is made, it shall be deemed effective at the pleasure of the Board of Directors. When one or more directors shall resign from the Board of Directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take

effect when such resignation or resignations shall become effective, and each Director so chosen shall hold office for the unexpired portion of the term of the Director whose place shall be vacated and until his successor shall have been duly elected and qualified.

Section 4.7 Removal. Any or all of the directors (other than the directors elected by the holders of any series of Preferred Stock of the corporation, voting separately as a series or together with one or more other such series, as the case may be) may be removed only for cause and only by the affirmative vote of the holders of at least a majority in voting power of all the then outstanding shares of stock of the corporation entitled to vote thereon, voting together as a single class.

Section 4.8 Meetings.

(a) **Regular Meetings.** Unless otherwise restricted by the Certificate of Incorporation, regular meetings of the Board of Directors may be held at any time or date and at any place within or without the State of Delaware which has been designated by the Board of Directors. No notice shall be required for regular meetings of the Board of Directors.

(b) **Special Meetings.** Unless otherwise restricted by the Certificate of Incorporation, special meetings of the Board of Directors may be held at any time and place within or without the State of Delaware whenever called in writing, including electronic communication, by the Chair of the Board, the Chief Executive Officer and President, any two directors or any one director in the event there is only one director in office.

(c) **Meetings by Electronic Communications Equipment.** Any member of the Board of Directors, or of any committee thereof, may participate in a meeting by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

(d) **Notice of Special Meetings.** Notice of the time and place of all special meetings of the Board of Directors shall be delivered orally or in writing, by telephone, including a voice messaging system or other system or technology designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means, during normal business hours, at least twenty-four (24) hours before the date and time of the meeting. If notice is sent by U.S. mail, it shall be sent by first class mail, charges prepaid, at least three (3) days before the date of the meeting.

(e) **Waiver of Notice.** Notice of any meeting may be waived in writing, or by electronic transmission, at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. The transaction of all business at any meeting of the Board of Directors, or any committee thereof, however called or noticed, or wherever held, shall be as valid as though the business was transacted at a meeting duly held after regular call and notice, if a quorum be present and if, either before or after the meeting, each of the directors

not present who did not receive notice shall sign a written waiver of notice or shall waive notice by electronic transmission. All such waivers shall be filed with the corporate records or made a part of the minutes of the meeting.

Section 4.9 Quorum and Voting.

(a) Unless the Certificate of Incorporation requires a greater number, and except with respect to indemnification questions arising under Section 12.1 hereof, for which a quorum shall be one-third of the exact number of directors fixed from time to time, and except with respect to certain transactions questions arising under Section 9.1, for which a quorum is set by Section 9.2 hereof, a quorum of the Board of Directors shall consist of a majority of the exact number of directors fixed from time to time by the Board of Directors in accordance with the Certificate of Incorporation; *provided, however*, at any meeting whether a quorum be present or otherwise, a majority of the directors present may adjourn from time to time until the time fixed for the next regular meeting of the Board of Directors, without notice other than by announcement at the meeting.

(b) At each meeting of the Board of Directors at which a quorum is present, all questions and business shall be determined by the affirmative vote of a majority of the directors present, unless a different vote be required by law, the Certificate of Incorporation or these Bylaws.

Section 4.10. Action without Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission, and such writing or writings or transmission or transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 4.11 Fees and Compensation. Directors shall be entitled to such compensation for their services as may be approved by the Board of Directors, including, if so approved, by resolution of the Board of Directors, a fixed sum and expenses of attendance, if any, for attendance at each regular or special meeting of the Board of Directors and at any meeting of a committee of the Board of Directors. Nothing herein contained shall be construed to preclude any director from serving the corporation in any other capacity as an officer, agent, employee, or otherwise and receiving compensation therefor.

Section 4.12 Committees.

(a) **Committees.** The Board of Directors may, from time to time, appoint such committees as may be permitted by law. Such other committees appointed by the Board of Directors shall consist of one (1) or more members of the Board of Directors and shall have such powers and perform such duties as may be prescribed by the resolution or resolutions creating such committees.

(b) **Term.** The Board of Directors, subject to any requirements of any outstanding series of Preferred Stock, and the provisions of subsection (a) of this Section 4.12 may at any time increase or decrease the number of members of a committee or terminate the existence of a committee. The membership of a committee member shall terminate on the date of his death or voluntary resignation from the committee or from the Board of Directors. The Board of Directors may at any time for any reason remove any individual committee member and the Board of Directors may fill any committee vacancy created by death, resignation, removal or increase in the number of members of the committee. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee, and, in addition, in the absence or disqualification of any member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member.

(c) **Meetings.** Unless the Board of Directors shall otherwise provide, regular meetings of any committee appointed pursuant to this Section 4.12 shall be held at such times and places as are determined by the Board of Directors, or by any such committee, and when notice thereof has been given to each member of such committee, no further notice of such regular meetings need be given thereafter. Special meetings of any such committee may be held at any place which has been determined from time to time by such committee, and may be called by the chair of such committee or a member of such committee, upon notice to the members of such committee of the time and place of such special meeting given in the manner provided for the giving of notice to members of the Board of Directors of the time and place of special meetings of the Board of Directors. Notice of any special meeting of any committee may be waived in writing or by electronic transmission at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends such special meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Unless otherwise provided by the Board of Directors in the resolutions authorizing the creation of the committee, a majority of the authorized number of members of any such committee shall constitute a quorum for the transaction of business, and the act of a majority of those present at any meeting at which a quorum is present shall be the act of such committee.

Section 4.13 Organization. At every meeting of the directors, the Chair of the Board of Directors, or, if a Chair has not been appointed or is absent, the Chief Executive Officer and President (if a director), or, if the Chief Executive Officer and President has not been appointed or is absent the most senior Vice President (if a director), or, in the absence of any such person, a chair of the meeting chosen by a majority of the directors present, shall preside over the meeting. The Secretary, or in his or her absence, any person directed to do so by the chair of the meeting, shall act as secretary of the meeting.

Section 4.14 Director Emeritus.

(a) The Board of Directors may, subject to the limitations, conditions, and qualifications of this section, appoint one or more individuals to serve as a Director Emeritus or Director Emerita of the corporation (any Director Emeritus / Emerita is referred to herein as a “Director Emeritus”). A Director Emeritus must (i) be a former director of the corporation, and (ii) be an individual whose exemplary service and contribution to the corporation, as a director or otherwise, merits such an honorary designation, which determination shall be made by the Board of Directors in its discretion.

(b) A Director Emeritus shall serve in such capacity until the first to occur of (i) the termination of such individual’s appointment at any time by the Board of Directors, in its discretion, for any reason or no reason, or (ii) such individual’s resignation or death.

(c) A Director Emeritus may attend meetings of the Board of Directors as invited by the Board of Directors and may attend meetings of any committee of the Board of Directors as invited by any such committee, but they shall not be permitted to attend or remain in attendance (i) during any executive session of the Board of Directors or committee, as applicable, (ii) at any meeting where privileged matters are to be discussed or considered, or (iii) at any meeting involving the discussion or consideration of matters with respect to which such individual has a material monetary or other conflict of interest, unless such interest is disclosed to the Board of Directors or committee in advance and the Board of Directors or committee, as applicable, consents to such individual’s attendance.

(d) If present at a meeting of the Board of Directors or a committee of the Board of Directors, a Director Emeritus may participate in the discussions occurring at such meetings as determined to be appropriate by the Board of Directors or committee, as applicable; however, (i) they shall not be entitled to notice of any such meetings, (ii) shall not be counted for quorum purposes at any such meetings, (iii) shall not vote or otherwise formally participate with respect to any resolutions of the Board of Directors or committee, as applicable, or any matter brought before the Board of Directors or committee, as applicable, and (iv) shall not have any corporate governance duties or rights with respect to the corporation.

(e) Any person holding the position of Director Emeritus shall not be considered a director or officer under the corporation’s Certificate of Incorporation, these Bylaws, or the DGCL, and shall have no power or authority to manage the affairs of the corporation. Notwithstanding the foregoing, a Director Emeritus shall be subject to the same policies to which directors are subject, and a Director Emeritus shall be entitled throughout their service to the same indemnification benefits and protections accorded to directors under Article 12 of these Bylaws.

(f) The corporation may enter into such indemnification agreements with a Director Emeritus as the corporation and the Director Emeritus may agree.

(g) Unless otherwise determined by the Board of Directors, in its sole discretion, a Director Emeritus shall not be entitled to receive fees for such service. Notwithstanding the foregoing, a Director Emeritus shall be entitled to be reimbursed for reasonable travel and other out-of-pocket business expenses incurred in connection with attendance at meetings of the Board of Directors and its committees or other corporation events, provided that such expenses have been approved by the Board of Directors or committee(s) prior to being incurred.

(h) A person holding the position of Director Emeritus shall be obligated to not disclose any confidential information of the corporation obtained in such individual's capacity as a Director Emeritus.

ARTICLE 5

OFFICERS

Section 5.1 Officers Designated. The officers of the corporation shall include, if and when designated by the Board of Directors, the Chair of the Board of Directors (provided that notwithstanding anything to the contrary contained in these Bylaws, the Chair of the Board of Directors shall not be deemed an officer of the corporation unless so designated by the Board of Directors), the Chief Executive Officer and President, one or more Vice Presidents, the Secretary, the Chief Financial Officer and the Treasurer. The Board of Directors may also appoint one or more Assistant Secretaries, Assistant Treasurers and such other officers and agents with such powers and duties as it shall deem necessary. The Board of Directors may assign such additional titles to one or more of the officers as it shall deem appropriate. Any one person may hold any number of offices of the corporation at any one time unless specifically prohibited therefrom by law. The salaries and other compensation of the officers of the corporation shall be fixed by or in the manner designated by the Board of Directors.

Section 5.2 Tenure and Duties of Officers.

(a) **General.** All officers shall hold office at the pleasure of the Board of Directors and until their successors shall have been duly elected and qualified, unless sooner removed. Any officer elected or appointed by the Board of Directors may be removed at any time by the Board of Directors. If the office of any officer becomes vacant for any reason, the vacancy may be filled by the Board of Directors.

(b) **Duties of Chair of the Board of Directors.** The Chair of the Board of Directors, when present, shall preside at all meetings of the stockholders and the Board of Directors. The Chair of the Board of Directors shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors shall designate from time to time.

(c) **Duties of Chief Executive Officer and President.** The Chief Executive Officer and President shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chair of the Board of Directors has been appointed and is present.

The Chief Executive Officer and President shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the corporation, perform other duties commonly incident to the office, and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

(d) **Duties of Vice Presidents.** The Vice Presidents may assume and perform the duties of the President in the absence or disability of the President or whenever the office of President is vacant. The Vice Presidents shall perform other duties commonly incident to their office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

(e) **Duties of Secretary.** The Secretary shall attend all meetings of the stockholders and of the Board of Directors and shall record all acts and proceedings thereof in the minute book of the corporation. The Secretary shall give notice in conformity with these Bylaws of all meetings of the stockholders and of all meetings of the Board of Directors and any committee thereof requiring notice. The Secretary shall perform all other duties provided for in these Bylaws and other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors shall designate from time to time. The Chief Executive Officer and President may direct any Assistant Secretary or other office or director to assume and perform the duties of the Secretary in the absence or disability of the Secretary, and each Assistant Secretary shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer and President shall designate from time to time.

(f) **Duties of Chief Financial Officer.** The Chief Financial Officer shall keep or cause to be kept the books of account of the corporation in a thorough and proper manner and shall render statements of the financial affairs of the corporation in such form and as often as required by the Board of Directors or the Chief Executive Officer and President. The Chief Financial Officer, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the corporation. The Chief Financial Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer and President shall designate from time to time. The Chief Executive Officer and President may direct the Vice President of Finance, Treasurer or any Assistant Treasurer, or the Controller or Assistant Controller, to assume and perform the duties of the Chief Financial Officer in the absence or disability of the Chief Financial Officer and, in the absence or disability of the Chief Financial Officer, each Vice President of Finance, Treasurer or any Assistant Treasurer, or the Controller or Assistance Controller shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer and President shall designate from time to time.

(g) **Treasurer.** The Treasurer shall have such duties as may be specified by the Chief Financial Officer to assist the Chief Financial Officer in the performance of his or her duties to perform such other duties and have other powers as may from time to time be prescribed by the Board of Directors or the Chief Executive Officer and President.

(h) **Assistant Treasurer.** The Chief Executive Officer and President may direct any Assistant Treasurer to assume and perform the duties of the Treasurer in the absence or disability of the Treasurer, and each Assistant Treasurer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer and President shall designate from time to time.

Section 5.3 Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

Section 5.4 Resignations. Any officer may resign at any time by giving notice in writing or by electronic transmission to the Board of Directors or to the President or to the Secretary. Any such resignation shall be effective when received by the person or persons to whom such notice is given, unless a later time is specified therein, in which event the resignation shall become effective at such later time. Unless otherwise specified in such notice, the acceptance of any such resignation shall not be necessary to make it effective. Any resignation shall be without prejudice to the rights, if any, of the corporation under any contract with the resigning officer.

Section 5.5 Removal. Any officer may be removed from office at any time, either with or without cause, by the affirmative vote of a majority of the directors in office at the time, or by the unanimous written or electronic consent of the directors in office at the time, or by any committee of the Board of Directors or by superior officers upon whom such power of removal may have been conferred by the Board of Directors.

ARTICLE 6

EXECUTION OF CORPORATE INSTRUMENTS AND VOTING OF SECURITIES OWNED BY THE CORPORATION

Section 6.1 Execution of Corporate Instruments.

(a) The Board of Directors may, in its discretion, determine the method and designate the signatory officer or officers, or other person or persons, to execute on behalf of the corporation any corporate instrument or document, or to sign on behalf of the corporation the corporate name without limitation, or to enter into contracts on behalf of the corporation, except where otherwise provided by law or these Bylaws, and such execution or signature shall be binding upon the corporation.

(b) Unless otherwise specifically determined by the Board of Directors or otherwise required by law, promissory notes, deeds of trust, mortgages and other evidences of indebtedness of the corporation, and other corporate instruments or documents requiring the corporate seal, if any, and certificates of shares of stock owned by the corporation, shall be executed, signed or endorsed by the Chair of the Board of Directors, or the Chief Executive Officer and President or any Vice President, and by the Secretary or Treasurer or any Assistant Secretary or Assistant Treasurer. All other instruments and documents requiring the corporate

signature, but not requiring the corporate seal, may be executed as aforesaid or in such other manner as may be directed by the Board of Directors.

(c) Unless authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge the corporation's credit or to render it liable for any purpose or for any amount.

(d) All checks and drafts drawn on banks or other depositories on funds to the credit of the corporation or in special accounts of the corporation shall be signed by such person or persons as the Board of Directors shall authorize so to do.

Section 6.2 Voting of Securities Owned by the Corporation. All stock and other securities of other corporations owned or held by the corporation for itself, or for other parties in any capacity, shall be voted, and all proxies with respect thereto shall be executed, by the person authorized so to do by resolution of the Board of Directors, or, in the absence of such authorization, by the Chair of the Board of Directors, the Chief Executive Officer and President, or any Vice President.

ARTICLE 7

SHARES OF STOCK

Section 7.1 Form and Execution of Certificates. The shares of the corporation shall be represented by certificates, or shall be uncertificated. Certificates for the shares of stock of the corporation shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock in the corporation represented by certificates shall be entitled to have a certificate signed by or in the name of the corporation by the Chair of the Board of Directors, or the Chief Executive Officer and President, or any Vice President and by the Treasurer or Assistant Treasurer or the Secretary or Assistant Secretary, certifying the number of shares owned by the holder in the corporation. Any or all of the signatures on the certificate may be facsimiles. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent, or registrar before such certificate is issued, it may be issued with the same effect as if he were such officer, transfer agent, or registrar at the date of issue. Each certificate shall state upon the face or back thereof, in full or in summary, all of the powers, designations, preferences, and rights, and the limitations or restrictions of the shares authorized to be issued or shall, except as otherwise required by law, set forth on the face or back a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional, or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the corporation shall send to the registered owner thereof a written notice containing the information required by the DGCL or a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating,

optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Section 7.2 Lost Certificates. A new certificate or certificates shall be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen, or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen, or destroyed and on such terms and conditions as the corporation may require. The corporation may require, as a condition precedent to the issuance of a new certificate or certificates, the owner of such lost, stolen, or destroyed certificate or certificates, or the owner's legal representative, to agree to indemnify the corporation in such manner as it shall require or to give the corporation a surety bond in such form and amount as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen, or destroyed.

Section 7.3 Transfers.

(a) Transfers of record of shares of stock of the corporation shall be made only upon the corporation's books by the holders thereof, in person or by attorney duly authorized, and upon the surrender of a properly endorsed certificate or certificates for a like number of shares and proper evidence of compliance with other conditions of applicable law, by contract or otherwise to rightful transfer.

(b) Upon receipt of proper transfer instructions and proper evidence of compliance of other conditions of applicable law, by contract or otherwise to rightful transfer from the registered owner of the uncertificated or certificated shares, such uncertificated or certificated shares, as applicable, shall be cancelled and issuance of new equivalent uncertificated shares or certificated shares shall be made to the person entitled thereto and the transaction shall be recorded upon the books of the corporation.

(c) The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

Section 7.4 Fixing Record Dates.

(a) In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix, in advance, a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, subject to applicable law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to

vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board of Directors may fix a new record date for the adjourned meeting.

(b) In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

Section 7.5 Registered Stockholders. The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE 8

OTHER SECURITIES OF THE CORPORATION

All bonds, debentures and other corporate securities of the corporation, other than stock certificates (covered in Section 7.1), may be signed by the Chair of the Board of Directors, the Chief Executive Officer and President, or any Vice President, or such other person as may be authorized by the Board of Directors, and the corporate seal impressed thereon or a facsimile of such seal imprinted thereon and attested by the signature of the Secretary or an Assistant Secretary, or the Chief Financial Officer or Treasurer or an Assistant Treasurer; *provided, however*, that where any such bond, debenture or other corporate security shall be authenticated by the manual signature, or where permissible facsimile signature, of a trustee under an indenture pursuant to which such bond, debenture or other corporate security shall be issued, the signatures of the persons signing and attesting the corporate seal on such bond, debenture or other corporate security may be the imprinted facsimile of the signatures of such persons. Interest coupons appertaining to any such bond, debenture or other corporate security, authenticated by a trustee as aforesaid, shall be signed by the Treasurer or an Assistant Treasurer of the corporation or such other person as may be authorized by the Board of Directors or bear imprinted thereon the facsimile signature of such person. In case any officer who shall have signed or attested any bond, debenture or other corporate security, or whose facsimile signature shall appear thereon or on any such interest coupon, shall have ceased to be such officer before the bond, debenture or other corporate security so signed or attested shall have been delivered, such bond, debenture or other corporate security nevertheless may be adopted by the corporation and issued and delivered as though the person who signed the same or whose facsimile signature shall have been used thereon had not ceased to be such officer of the corporation.

ARTICLE 9

CERTAIN TRANSACTIONS

Section 9.1 Conflicting Transactions for Directors and Officers. Except for a controlling stockholder transaction described under Section 9.2 or Section 9.3 of this Article, an act or transaction involving or between the corporation, or one or more of the corporation's subsidiaries, on the one hand, and one or more of the corporation's directors or officers, on the other hand, or involving or between the corporation or one or more of the corporation's subsidiaries, on the one hand, and any other corporation, partnership (general or limited), limited liability company, statutory trust, association, or any other entity or organization in which one or more of its directors or officers are directors, stockholders, partners, managers, members, or officers, or have a financial interest, on the other hand, may not be the subject of equitable relief, or give rise to an award of damages, against a director or officer of the corporation because of the foregoing circumstances or the receipt of any benefit by any such director, officer, entity, or organization or because the director or officer is present at or participates in the meeting of the board or committee which authorizes the act or transaction or was involved in the initiation, negotiation, or approval of the act or transaction (including by virtue of a director's vote being counted for such purpose), if:

- (a) The material facts as to the director's or officer's relationship or interest and as to the act or transaction, including any involvement in the initiation, negotiation, or approval of the act or transaction, are disclosed or are known to all members of the board of directors or a committee of the board of directors, and the board or committee in good faith and without gross negligence authorizes the act or transaction by the affirmative votes of a majority of the disinterested directors then serving on the board of directors or such committee (as applicable), even though the disinterested directors be less than a quorum; provided that if a majority of the directors are not disinterested directors with respect to the act or transaction, such act or transaction shall be approved (or recommended for approval) by a committee of the board of directors that consists of two or more directors, each of whom the board of directors has determined to be a disinterested director with respect to the act or transaction; or
- (b) The act or transaction is approved or ratified by an informed, uncoerced, affirmative vote of a majority of the votes cast by the disinterested stockholders; or
- (c) The act or transaction is fair as to the corporation and the corporation's stockholders.

Section 9.2 Conflicting Transactions for Controlling Stockholders (Non-Going Private Transactions). A controlling stockholder transaction (other than any going private transaction) may not be the subject of equitable relief, or give rise to an award of damages, against a director or officer of the corporation or any controlling stockholder or member of a control group, by reason of a claim based on a breach of fiduciary duty by a director, officer, controlling stockholder, or member of a control group, if:

(a) The material facts as to such controlling stockholder transaction (including the controlling stockholder's or control group's interest therein) are disclosed or are known to all members of a committee of the board of directors to which the board of directors has expressly delegated the authority to negotiate (or oversee the negotiation of) and to reject such controlling stockholder transaction, and such controlling stockholder transaction is approved (or recommended for approval) in good faith and without gross negligence by a majority of the disinterested directors then serving on the committee; provided that the committee consists of two or more directors, each of whom the board of directors has determined to be a disinterested director with respect to the controlling stockholder transaction; or

(b) Such controlling stockholder transaction is conditioned, by its terms, as in effect at the time it is submitted to stockholders for their approval or ratification, on the approval of or ratification by disinterested stockholders, and such controlling stockholder transaction is approved or ratified by an informed, uncoerced, affirmative vote of a majority of the votes cast by the disinterested stockholders; or

(c) Such controlling stockholder transaction is fair as to the corporation and the corporation's stockholders.

Section 9.3 Conflicting Transactions for Controlling Stockholders (Going Private Transactions). A controlling stockholder transaction constituting a going private transaction may not be the subject of equitable relief, or give rise to an award of damages, against a director or officer of the corporation or any controlling stockholder or member of a control group by reason of a claim based on breach of fiduciary duty by a director, officer, controlling stockholder, or member of a control group, if:

(a) Such controlling stockholder transaction is approved (or recommended for approval) in accordance with Section 9.2(a) of this Article and approved in accordance with Section 9.2(b) of this Article; or

(b) Such controlling stockholder transaction is fair as to the corporation and the corporation's stockholders.

Section 9.4 Quorum

(a) Common or interested directors may be counted in determining the presence of a quorum at a meeting of the board of directors or of a committee which authorizes the act or transaction.

(b) Any director of the corporation shall be presumed to be a disinterested director with respect to an act or transaction to which such director is not a party if the board of directors shall have determined that such director satisfies the applicable criteria for determining director independence from the corporation and, if applicable with respect to the act or transaction, the controlling stockholder or control group, under the rules (and interpretations thereof) promulgated by the New York Stock Exchange (American) or such other national securities exchange that the corporation's shares are then-listed (treating the applicable

controlling stockholder and control group as if the controlling stockholder and control group were the corporation for purposes of applying such criteria to determine independence from a controlling stockholder or control group), which presumption shall be heightened and may only be rebutted by substantial and particularized facts that such director has a material interest in such act or transaction or has a material relationship with a person with a material interest in such act or transaction.

(c) The designation, nomination, or vote in the election of the director to the board of directors by any person that has a material interest in an act or transaction shall not, of itself, be evidence that a director is not a disinterested director with respect to an act or transaction to which such director is not a party.

(d) No person shall be deemed a controlling stockholder unless such person satisfies the criteria in Section 9.5(b) of this Article. No two or more persons that are not controlling stockholders shall be a control group unless they satisfy the criteria in Section 9.5(a) of this Article.

(e) No person who is a controlling stockholder or member of a control group shall be liable in such capacity to the corporation or its stockholders for monetary damages for breach of fiduciary duty other than for:

(i) A breach of the duty of loyalty to the corporation or the other stockholders;

(ii) Acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; or

(iii) Any transaction from which the person derived an improper personal benefit.

(f) Nothing in Section 9.1, 9.2, or 9.3 of this Article shall:

(i) Limit or eliminate the right of any person to seek equitable relief on the grounds that an act or transaction, including a controlling stockholder transaction, was not authorized or approved in compliance with the procedures set forth in the DGCL, was not authorized or approved in compliance with the certificate of incorporation or these bylaws, or is in violation of any plan, agreement, or order of any governmental authority to which the corporation is a party or subject; or

(ii) Limit judicial review for purposes of injunctive relief of provisions or devices designed or intended to deter, delay, or preclude a change of control or other transaction involving the corporation or a change in the composition of the board of directors; or

(iii) Limit or eliminate the right of any person to seek relief on the grounds that a stockholder or other person knowingly aided and abetted a breach of fiduciary duty by one or more of the directors of the corporation.

(g) Shares irrevocably accepted for purchase or exchange pursuant to an offer contemplated by § 251(h) of the DGCL shall be deemed voted in favor of the act or transaction and shares owned or controlled by disinterested stockholders that have not been irrevocably accepted for purchase or exchange pursuant to such an offer shall be deemed voted against the act or transaction for purposes of determining whether the act or transaction has been approved for purposes of Section 9.1(b), Section 9.2(b) and Section 9.3(a) of this Article.

Section 9.5 Definitions. For purposes of this Article:

(a) “Control group” means two or more persons that are not controlling stockholders that, by virtue of an agreement, arrangement, or understanding between or among such persons, constitute a controlling stockholder.

(b) “Controlling stockholder” means any person that, together with such person’s affiliates and associates:

(i) Owns or controls a majority in voting power of the outstanding stock of the corporation entitled to vote generally in the election of directors or in the election of directors who have a majority in voting power of the votes of all directors on the board of directors;

(ii) Has the right, by contract or otherwise, to cause the election of nominees who are selected at the discretion of such person and who constitute either a majority of the members of the board of directors or directors entitled to cast a majority in voting power of the votes of all directors on the board of directors; or

(iii) Has the power functionally equivalent to that of a stockholder that owns or controls a majority in voting power of the outstanding stock of the corporation entitled to vote generally in the election of directors by virtue of ownership or control of at least one-third in voting power of the outstanding stock of the corporation entitled to vote generally in the election of directors or in the election of directors who have a majority in voting power of the votes of all directors on the board of directors and power to exercise managerial authority over the business and affairs of the corporation.

(c) “Controlling stockholder transaction” means an act or transaction between the corporation or one or more of its subsidiaries, on the one hand, and a controlling stockholder or a control group, on the other hand, or an act or transaction from which a controlling stockholder or a control group receives a financial or other benefit not shared with the corporation’s stockholders generally.

(d) “Disinterested director” means a director who is not a party to the act or transaction and does not have a material interest in the act or transaction or a material relationship with a person that has a material interest in the act or transaction.

(e) “Disinterested stockholder” means any stockholder that does not have a material interest in the act or transaction at issue or, if applicable, a material relationship with the

controlling stockholder or other member of the control group, or any other person that has a material interest in the act or transaction.

(f) “Going private transaction” means:

(i) So long as the corporation has a class of equity securities subject to § 12(g) or 15(d) of the Securities Exchange Act of 1934 [15 U.S.C. § 78l(g) or § 78o(d)] or listed on a national securities exchange, a “Rule 13e-3 transaction” (as defined in 17 C.F.R. § 240.13e-3(a)(3) or any successor provision); and

(ii) If the corporation no longer has any class of equity securities subject to § 12(g) or 15(d) of the Securities Exchange Act of 1934 [15 U.S.C. § 78l(g) or § 78o(d)] or listed on a national securities exchange, any controlling stockholder transaction, including a merger, recapitalization, share purchase, consolidation, amendment to the certificate of incorporation, tender or exchange offer, conversion, transfer, domestication or continuance, pursuant to which all or substantially all of the shares of the corporation’s capital stock held by the disinterested stockholders (but not those of the controlling stockholder or control group) are cancelled, converted, purchased, or otherwise acquired or cease to be outstanding.

(g) “Material interest” means an actual or potential benefit, including the avoidance of a detriment, other than one which would devolve on the corporation or the stockholders generally, that (i) in the case of a director, would reasonably be expected to impair the objectivity of the director’s judgment when participating in the negotiation, authorization, or approval of the act or transaction at issue and (ii) in the case of a stockholder or any other person (other than a director), would be material to such stockholder or such other person.

(h) “Material relationship” means a familial, financial, professional, employment, or other relationship that (i) in the case of a director, would reasonably be expected to impair the objectivity of the director’s judgment when participating in the negotiation, authorization, or approval of the act or transaction at issue and (ii) in the case of a stockholder, would be material to such stockholder.

ARTICLE 10

DIVIDENDS

Section 10.1 Declaration of Dividends. Dividends upon the capital stock of the corporation, subject to the provisions of the Certificate of Incorporation and applicable law, if any, may be declared by the Board of Directors pursuant to law at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation and applicable law.

Section 10.2 Dividend Reserve. Before payment of any dividend, there may be set aside out of any funds of the corporation available for dividends such sum or sums as the Board of Directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of

the corporation, or for such other purpose as the Board of Directors shall think conducive to the interests of the corporation, and the Board of Directors may modify or abolish any such reserve in the manner in which it was created.

ARTICLE 11

FISCAL YEAR

The fiscal year of the corporation shall be fixed by resolution of the Board of Directors.

ARTICLE 12

INDEMNIFICATION

Section 12.1. Indemnification of Directors, Executive Officers, Other Officers, Employees and Other Agents.

(a) **Directors and Executive Officers.** The corporation shall indemnify its directors and executive officers (for the purposes of this Article 12, “executive officers” shall have the meaning defined in Rule 3b-7 promulgated under the 1934 Act) to the fullest extent not prohibited by the DGCL or any other applicable law; *provided, however*, that the corporation may modify the extent of such indemnification by individual contracts with its directors and executive officers.

(b) **Other Officers, Employees and Other Agents.** The corporation shall have power to indemnify its other officers, employees and other agents as set forth in the DGCL or any other applicable law. The Board of Directors shall have the power to delegate the determination of whether indemnification shall be given to any such person (other than as specified in clause (a) above) to such officers or other persons as the Board of Directors shall determine.

(c) **Expenses.** The corporation shall advance to any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or executive officer, of the corporation, or is or was serving at the request of the corporation as a director or executive officer of another corporation, partnership, joint venture, trust or other enterprise, prior to the final disposition of the proceeding, promptly following request therefor, all expenses incurred by any director or executive officer in connection with such proceeding; *provided, however*, that if the DGCL requires, an advancement of expenses incurred by a director or an executive officer in his or her capacity as a director or an executive officer (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to the corporation of an undertaking (hereinafter an “undertaking”), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (hereinafter a “final

adjudication”) that such indemnitee is not entitled to be indemnified for such expenses under this Section 12.1 or otherwise.

Notwithstanding the foregoing, unless otherwise determined pursuant to paragraph (e) of this Section 12.1, no advance shall be made by the corporation to an executive officer of the corporation (except by reason of the fact that such executive officer is or was a director of the corporation, in which event this paragraph shall not apply) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made (i) by a majority vote of directors who were not parties to the proceeding, even if not a quorum, or (ii) by a committee of such directors designated by a majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or such directors so direct, by independent legal counsel in a written opinion, that the facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the corporation.

(d) **Enforcement.** Without the necessity of entering into an express contract, all rights to indemnification and advances to directors and executive officers under this Section 12.1 shall be deemed to be contractual rights and be effective to the same extent and as if provided for in a contract between the corporation and the director or executive officer. Any right to indemnification or advances granted by this Section 12.1 to a director or executive officer shall be enforceable by or on behalf of the person holding such right in any court of competent jurisdiction if (i) the claim for indemnification or advances is denied, in whole or in part, or (ii) no disposition of such claim is made within ninety (90) days of request therefor. The claimant in such enforcement action, if successful in whole or in part, shall be entitled to be paid also the expense of prosecuting the claim. In connection with any claim for indemnification, the corporation shall be entitled to raise as a defense to any such action that the claimant has not met the standards of conduct that make it permissible under the DGCL or any other applicable law for the corporation to indemnify the claimant for the amount claimed. In connection with any claim by an executive officer of the corporation (except in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such executive officer is or was a director of the corporation) for advances, the corporation shall be entitled to raise a defense as to any such action clear and convincing evidence that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the corporation, or with respect to any criminal action or proceeding that such person acted without reasonable cause to believe that his conduct was lawful. Neither the failure of the corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because he has met the applicable standard of conduct set forth in the DGCL or any other applicable law, nor an actual determination by the corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that claimant has not met the applicable standard of conduct. In any suit brought by a director or executive officer to enforce a right to

indemnification or to an advancement of expenses hereunder or brought by the corporation to recover an advancement of expenses pursuant to the terms of any undertaking, the burden of proving that the director or executive officer is not entitled to be indemnified, or to such advancement of expenses under this Section 12.1 or otherwise shall be on the corporation.

(e) **Non-Exclusivity of Rights.** The rights conferred on any person by this Section 12.1 shall not be exclusive of any other right which such person may have or hereafter acquire under any applicable statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advances, to the fullest extent not prohibited by the DGCL, or by any other applicable law.

(f) **Survival of Rights.** The rights conferred on any person by this Bylaw shall continue as to a person who has ceased to be a director or executive officer and shall inure to the benefit of the heirs, executors and administrators of such a person.

(g) **Insurance.** To the fullest extent permitted by the DGCL, or any other applicable law, the corporation, upon approval by the Board of Directors, may purchase insurance on behalf of any person required or permitted to be indemnified pursuant to this Section 12.1.

(h) **Amendments.** Any amendment, alteration or repeal of this Section 12.1 that adversely affects any right of an indemnitee or its successors shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment or repeal.

(i) **Saving Clause.** If this Section 12.1 or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the corporation shall nevertheless indemnify each director and executive officer to the full extent not prohibited by any applicable portion of this Section 12.1 that shall not have been invalidated, or by any other applicable law. If this Section 12.1 shall be invalid due to the application of the indemnification provisions of another jurisdiction, then the corporation shall indemnify each director and executive officer to the full extent under any other applicable law.

(j) **Certain Definitions.** For the purposes of this Bylaw, the following definitions shall apply:

(1) The term “proceeding” shall be broadly construed and shall include, without limitation, the investigation, preparation, prosecution, defense, settlement, arbitration and appeal of, and the giving of testimony in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative.

(2) The term “expenses” shall be broadly construed and shall include, without limitation, court costs, attorneys’ fees, witness fees, fines, amounts paid in settlement or judgment, interest assessments and any other costs and expenses of any nature or kind incurred in connection with any proceeding.

(3) The term the “corporation” shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Section 12.1 with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

(4) References to a “director,” “executive officer,” “officer,” “employee,” or “agent” of the corporation shall include, without limitation, situations where such person is serving at the request of the corporation as, respectively, a director, executive officer, officer, employee, trustee or agent of another corporation, partnership, joint venture, trust or other enterprise.

(5) References to “other enterprises” shall include employee benefit plans; references to “fines” shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to “serving at the request of the corporation” shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the corporation” as referred to in this Section 12.1.

ARTICLE 13

NOTICES

(a) **Notice to Stockholders.** Notice to stockholders of stockholder meetings shall be given as provided in Section 3.4 herein. Without limiting the manner by which notice may otherwise be given effectively to stockholders under any agreement or contract with such stockholder, and except as otherwise required by law, notice to stockholders for purposes other than stockholder meetings may be sent by U.S. mail or nationally recognized overnight courier, or by facsimile, telegraph or telex or by electronic mail or other electronic transmission in the manner provided in Section 232 of the DGCL.

(b) **Notice to Directors.** Any notice required to be given to any director may be given by the method stated in subsection (a), or by overnight delivery service, facsimile, telex

or telegram, except that such notice other than one which is delivered personally shall be sent to such address as such director shall have filed in writing with the Secretary, or, in the absence of such filing, to the last known post office address of such director.

(c) **Affidavit of Mailing.** An affidavit of mailing, executed by a duly authorized and competent employee of the corporation or its transfer agent appointed with respect to the class of stock affected, or other agent, specifying the name and address or the names and addresses of the stockholder or stockholders, or director or directors, to whom any such notice or notices was or were given, and the time and method of giving the same, shall in the absence of fraud, be prima facie evidence of the facts therein contained.

(d) **Time Notices Deemed Given.** All notices given by mail or by overnight delivery service, as above provided, shall be deemed to have been given as at the time of mailing, and all notices given by facsimile, telex or telegram or by electronic mail or other electronic means shall be deemed to have been given as of the sending time recorded at time of transmission.

(e) **Failure to Receive Notice.** The period or limitation of time within which any stockholder may exercise any option or right, or enjoy any privilege or benefit, or be required to act, or within which any director may exercise any power or right, or enjoy any privilege, pursuant to any notice sent in the manner above provided, shall not be affected or extended in any manner by the failure of such stockholder or such director to receive such notice.

(f) **Methods of Notice.** It shall not be necessary that the same method of giving notice be employed in respect of all recipients of notice, but one permissible method may be employed in respect of any one or more, and any other permissible method or methods may be employed in respect of any other or others.

(g) **Notice to Person with Whom Communication Is Unlawful.** Whenever notice is required to be given, under any provision of law or of the Certificate of Incorporation or Bylaws of the corporation, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under any provision of the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

(h) **Notice to Stockholders Sharing an Address.** Except as otherwise prohibited under DGCL, any notice given under the provisions of DGCL, the Certificate of Incorporation or the Bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Such consent shall have been deemed to have been given if such stockholder fails to object in writing to the corporation within sixty (60) days of having been given notice by the

corporation of its intention to send the single notice. Any consent shall be revocable by the stockholder by written notice to the corporation.

ARTICLE 14

AMENDMENTS

Subject to the limitation set forth in Section 12.1(h) of these Bylaws or the provisions of the Certificate of Incorporation, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the corporation. The stockholders shall also have power to adopt, amend or repeal the Bylaws of the corporation; *provided, however*, that, in addition to any vote of the holders of any class or series of stock of the corporation required by law or by the Certificate of Incorporation, such action by the stockholders shall require the affirmative vote of the holders of at least two-thirds ($66\frac{2}{3}\%$) of the voting power of all of the then-outstanding shares of the capital stock of the corporation entitled to vote generally in the election of directors, voting together as a single class.

ARTICLE 15

FORUM SELECTION SUPPLEMENTAL PROVISIONS

In supplement to, and not in replacement of, Section 9.2 of the corporation's Certificate of Incorporation, unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or if such court does not have subject matter jurisdiction another state or federal court (as appropriate) located within the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for with respect to claims of stockholders, when acting in their capacity as stockholders or in the right of the corporation, if such claims relate to the business of the corporation, the conduct of its affairs, or the rights or powers of the corporation or its stockholders, directors or officers.

In addition to the above, if any action the subject matter of which is within the scope of this Article 15 is filed in a court other than a court located within the State of Delaware (a "Foreign Action") in the name of any stockholder, such stockholder shall be deemed to have consented to: (a) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce this Article 15 (an "Enforcement Action"), and (b) having service of process made upon such stockholder in any such Enforcement Action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

To the fullest extent permitted by law, any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Article 15, these Bylaws, and the corporation's Certificate of Incorporation. Failure to enforce the foregoing provisions would cause the corporation irreparable harm and the corporation shall be entitled to equitable relief, including injunction and specific performance, to enforce the foregoing provisions.

New Form of Warrant Agreement

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

WARRANT AGREEMENT

BETWEEN

SERINA THERAPEUTICS, INC.

AND

JUVVENTURES (UK) LIMITED

THIS WARRANT AGREEMENT (this "*Warrant Agreement*"), dated as of January 31, 2025, is by and between Serina Therapeutics, Inc., a Delaware corporation (the "*Company*"), and JuvVentures (UK) Limited, a private limited company incorporated under the laws of England and Wales (including its successors and assigns, the "*Juvenescence*").

WHEREAS, pursuant to that certain Agreement, dated as of the date hereof, entered into by and between the Company and Juvenescence (the "*Agreement*"), the Company will issue 755,728 Incentive Warrants (the "*Warrants*") to Juvenescence; and

WHEREAS, each Warrant shall be exercisable at an exercise price equal to \$18.00 and expire on March 26, 2028, to purchase one share of Common Stock.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the parties hereto agree as follows:

- 1. DEFINITIONS.** Capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Agreement.
- 2. REGISTERED HOLDER.** Prior to due presentment for registration of a Permitted Transfer of any Warrant, the Company may deem and treat Juvenescence (the "*Registered Holder*") as the absolute owner of such Warrant and of each Warrant represented thereby (notwithstanding any notation of ownership or other writing on any physical certificate made by anyone other than the Company), for the purpose of any exercise thereof, and for all other purposes, and the Company shall not be affected by any notice to the contrary.
- 3. TERMS AND EXERCISE OF WARRANTS.**

3.1 **Warrant Price.** This Warrant Agreement entitles the Registered Holder thereof, subject to the provisions of this Warrant Agreement, to purchase from the Company up to 755,728 shares of Common Stock at the price of \$18.00 per Warrant, subject to the adjustments provided in [Section 4](#) hereof and in the last sentence of this [Section 3.1](#) (the "*Incentive Warrant Price*").

3.2 Duration of Warrants. A Warrant may be exercised only during the period (the “*Exercise Period*”) commencing on the date of issuance of the Warrant, and terminating at 5:00 p.m., New York City time on March 26, 2028 (the “*Expiration Date*”). Each Warrant not exercised on or before the applicable Expiration Date shall become void, and all rights thereunder and all rights in respect thereof under this Warrant Agreement shall cease at 5:00 p.m. New York City time on the applicable Expiration Date. The Company in its sole discretion may extend the duration of the Warrants by delaying the applicable Expiration Date; provided, that the Company shall provide at least five (5) days prior written notice of any such extension to Registered Holders of the applicable Warrants and, provided further that any such extension shall be identical in duration among all the Warrants of the same kind.

3.3 Exercise of Warrants.

3.3.1 Payment. Subject to the provisions of this Warrant Agreement, a Warrant may be exercised by the Registered Holder by delivering to the Company (i) the definitive warrant certificate evidencing the Warrants to be exercised, (ii) an election to purchase any shares of Common Stock pursuant to the exercise of a Warrant, properly completed and executed by the Registered Holder, and (iii) the payment in full of the applicable Warrant Price for each full share of Common Stock as to which the Warrant is exercised and any and all applicable taxes due in connection with the exercise of the Warrant, the exchange of the Warrant for the shares of Common Stock and the issuance of such shares of Common Stock, in lawful money of the United States, in good certified check or good bank draft payable to the Company.

3.3.2 Issuance of Shares of Common Stock on Exercise. As soon as practicable after the exercise of any Warrant and the clearance of the funds in payment of the Warrant Price, the Company shall issue to the Registered Holder of such Warrant the number of full shares of Common Stock to which such Registered Holder is entitled, registered in such name or names as may be directed by such Registered Holder. Notwithstanding the foregoing, the Company shall not be obligated to deliver any shares of Common Stock pursuant to the exercise of a Warrant and shall have no obligation to settle such Warrant exercise unless a valid exemption from registration is available or a registration statement under the Securities Act covering the issuance of the shares of Common Stock issuable upon the exercise of the Warrants (such shares of Common Stock, including any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect such shares of Common Stock, the “*Warrant Shares*”) is then effective and a current prospectus relating thereto is available. No Warrant shall be exercisable and the Company shall not be obligated to issue shares of Common Stock upon exercise of a Warrant unless such Warrant Shares have been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the Registered Holder of the Warrants. Subject to Section 4.6 of this Warrant Agreement, a Registered Holder of the Warrants may exercise its Warrants only for a whole number of shares of Common Stock. In no event will the Company be required to net cash settle the Warrant exercise.

3.3.3 Valid Issuance. All shares of Common Stock issued upon the proper exercise of a Warrant in conformity with this Warrant Agreement and the form of warrant shall be validly issued, fully paid and non-assessable.

3.3.4 Date of Issuance of Shares. Each person in whose name any book-entry position or certificate, as applicable, for shares of Common Stock is issued shall for all purposes be deemed to have become the holder of record of such shares of Common Stock on the date on which the Warrant was surrendered and payment of the applicable Warrant Price was made, irrespective of the date of delivery of such certificate, except that, if the date of such surrender and payment is a date when the share transfer books of the Company are closed, such person shall be deemed to have become the holder of such shares of Common Stock at the close of business on the next succeeding date on which the share transfer books or book-entry system are open.

3.3.5 Maximum Percentage. The Registered Holder may notify the Company in writing in the event it elects to be subject to the provisions contained in this subsection 3.3.5; however, the Registered Holder shall not be subject to this subsection 3.3.5 unless the Registered Holder makes such election. If the election is made by the Registered Holder, the Company shall not effect the exercise of the Warrant, and the Registered Holder shall not have the right to exercise such Warrant, to the extent that after giving effect to such exercise, the Registered Holder (together with the Registered Holder’s affiliates (as defined below)), to the Company’s actual knowledge, would beneficially own in excess of 9.999% (or such other amount as the Registered Holder may specify) (the “*Maximum Percentage*”) of the shares of Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by the Registered Holder

and its affiliates shall include the number of Warrant Shares with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock that would be issuable upon (x) exercise of the remaining, unexercised portion of the Warrant beneficially owned by the Registered Holder and its affiliates and (y) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by the Registered Holder and its affiliates (including, without limitation, any convertible notes or convertible preferred stock or warrants, including other Warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein. Except as set forth in the preceding sentence, for purposes of this paragraph, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”). For purposes of the Warrant, in determining the number of outstanding shares of Common Stock, the Registered Holder may rely on the number of outstanding shares of Common Stock as reflected in (1) the Company’s most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other public filing with the Commission as the case may be, (2) a more recent public announcement by the Company or (3) any other notice by the Company setting forth the number of shares of Common Stock outstanding. For any reason at any time, upon the written request of the Registered Holder, the Company shall, within two (2) Business Days, confirm orally and in writing to the Registered Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of equity securities of the Company by the Registered Holder and its affiliates since the date as of which such number of outstanding shares of Common Stock was reported. By written notice to the Company, the Registered Holder may from time to time increase or decrease the Maximum Percentage applicable to the Registered Holder to any other percentage specified in such notice; provided, however, that any such increase shall not be effective until the sixty-first (61st) day after such notice is delivered to the Company. The term “*affiliate*” shall have the meaning ascribed to such term in Rule 12b-2 under the Exchange Act (or any successor rule).

4. ADJUSTMENTS.

4.1 Stock Dividends. If after the date hereof, and subject to the provisions of Section 4.6 below, the number of outstanding shares of Common Stock is increased by a stock dividend payable in shares of Common Stock to all or substantially all holders of Common Stock, or by a split-up of shares of Common Stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of Common Stock issuable on exercise of each Warrant shall be increased in proportion to such increase in the outstanding shares of Common Stock.

4.2 Aggregation of Shares. If after the date hereof, and subject to the provisions of Section 4.6 hereof, the number of outstanding shares of Common Stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of Common Stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of Common Stock issuable on exercise of each Warrant shall be decreased in proportion to such decrease in outstanding shares of Common Stock.

4.3 Adjustments in Exercise Price. Whenever the number of shares of Common Stock purchasable upon the exercise of the Warrants is adjusted, as provided in Section 4.1 or Section 4.2 above, the applicable Warrant Price shall be adjusted (to the nearest cent) by multiplying such Warrant Price immediately prior to such adjustment by a fraction (x) the numerator of which shall be the number of shares of Common Stock purchasable upon the exercise of applicable Warrants immediately prior to such adjustment, and (y) the denominator of which shall be the number of shares of Common Stock so purchasable immediately thereafter.

4.4 Replacement of Securities upon Reorganization, etc. In case of any reclassification or reorganization of the outstanding shares of Common Stock (other than a change under Sections 4.1 or 4.2 hereof or that solely affects the par value of such shares of Common Stock), or in the case of any merger or consolidation of the Company with or into another corporation (other than a consolidation or merger in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of the outstanding shares of Common Stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the Registered Holder shall thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the Warrants and in lieu of the shares of Common Stock of the Company immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the Warrants would have received if such holder had exercised such Warrant(s) immediately prior to such event (the “*Alternative Issuance*”); provided, however, that (i) if the holders of the Common Stock were entitled to exercise a

right of election as to the kind or amount of securities, cash or other assets receivable upon such consolidation or merger, then the kind and amount of securities, cash or other assets constituting the Alternative Issuance for which each Warrant shall become exercisable shall be deemed to be the weighted average of the kind and amount received per share by the holders of the Common Stock in such consolidation or merger that affirmatively make such election, and (ii) if a tender, exchange or redemption offer shall have been made to and accepted by the holders of the Common Stock under circumstances in which, upon completion of such tender or exchange offer, the maker thereof, together with members of any group (within the meaning of Rule 13d-5(b)(1) under the Exchange Act (or any successor rule)) of which such maker is a part, and together with any affiliate or associate of such maker (within the meaning of Rule 12b-2 under the Exchange Act (or any successor rule)) and any members of any such group of which any such affiliate or associate is a part, own beneficially (within the meaning of Rule 13d-3 under the Exchange Act (or any successor rule)) more than 50% of the outstanding shares of Common Stock, the Registered Holder shall be entitled to receive as the Alternative Issuance, the highest amount of cash, securities or other property to which such holder would actually have been entitled as a stockholder if the Registered Holder had exercised the Warrant prior to the expiration of such tender or exchange offer, accepted such offer and all of the shares of Common Stock held by the Registered Holder had been purchased pursuant to such tender or exchange offer, subject to adjustments (from and after the consummation of such tender or exchange offer) as nearly equivalent as possible to the adjustments provided for in this Section 4 provided, further, that if less than 70% of the consideration receivable by the holders of the Common Stock in the applicable event is payable in the form of capital stock or shares in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the Registered Holder properly exercises the Warrant within thirty (30) days following the public disclosure of the consummation of such applicable event by the Company pursuant to a Current Report on Form 8-K filed with the Commission, the applicable Warrant Price shall be reduced by an amount (in dollars) equal to the difference of (i) the applicable Warrant Price in effect prior to such reduction minus (ii) (A) the Per Share Consideration (as defined below) (but in no event less than zero) minus (B) the Black-Scholes Warrant Value (as defined below). The "**Black-Scholes Warrant Value**" means the value of a Warrant immediately prior to the consummation of the applicable event based on the Black-Scholes Warrant Model for a Capped American Call on Bloomberg Financial Markets ("**Bloomberg**"). For purposes of calculating such amount, (1) Section 6 of this Agreement shall be taken into account, (2) the price of each share of Common Stock shall be the volume weighted average price of the shares of Common Stock as reported during the ten (10) trading day period ending on the trading day prior to the effective date of the applicable event, (3) the assumed volatility shall be the 90 day volatility obtained from the HVT function on Bloomberg determined as of the trading day immediately prior to the day of the announcement of the applicable event, and (4) the assumed risk-free interest rate shall correspond to the U.S. Treasury rate for a period equal to the remaining term of the Warrant. "**Per Share Consideration**" means (i) if the consideration paid to holders of the shares of Common Stock consists exclusively of cash, the amount of such cash per share of Common Stock, and (ii) in all other cases, the volume weighted average price of the shares of Common Stock as reported during the ten (10) trading day period ending on the trading day prior to the effective date of the applicable event. If any reclassification or reorganization also results in a change in shares of Common Stock covered by Section 4.1 then such adjustment shall be made pursuant to Sections 4.1, 4.2, 4.3 and this Section 4.4. The provisions of this Section 4.4 shall similarly apply to successive reclassifications, reorganizations, mergers or consolidations, sales or other transfers. In no event will the applicable Warrant Price be reduced to less than the par value per share issuable upon exercise of the Warrant.

4.5 Notices of Changes in Warrant. Upon every adjustment of the applicable Warrant Price or the number of Warrant Shares, the Company shall give written notice thereof to the Registered Holder, which notice shall state the applicable Warrant Price resulting from such adjustment and the increase or decrease, if any, in the number of shares of Common Stock purchasable at such price upon the exercise of a Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Upon the occurrence of any event specified in Sections 4.1, 4.2, 4.3 or 4.4, the Company shall give written notice of the occurrence of such event to the Registered Holder of the record date or the effective date of the event. Failure to give such notice, or any defect therein, shall not affect the legality or validity of such event.

4.6 No Fractional Shares. Notwithstanding any provision contained in this Warrant Agreement to the contrary, the Company shall not issue fractional shares of Common Stock upon the exercise of Warrants. If, by reason of any adjustment made pursuant to this Section 4, the Registered Holder would be entitled, upon the exercise of such Warrant, to receive a fractional interest in a share, the Company shall, upon such exercise, round down to the nearest whole number the number of shares of Common Stock to be issued to the Registered Holder.

4.7 Form of Warrant. This Warrant Agreement need not be changed because of any adjustment pursuant to this Section 4, and Warrants issued after such adjustment may state the same applicable Warrant Price and the same number of shares of Common Stock as is stated in the Warrants initially issued pursuant to this Warrant Agreement; provided, however, that the Company may at any time in its sole discretion make any change in the form of Warrant that the Company may deem appropriate and that does not affect the substance

thereof, and any Warrant thereafter issued or countersigned, whether in exchange or substitution for an outstanding Warrant or otherwise, may be in the form as so changed.

4.8 Other Events. In case any event shall occur as contemplated by Section 4.8 of that certain Warrant Agreement by and between the Company and Equiniti Trust Company as Warrant Agent dated as of March 19, 2024 (the "**Original Warrant Agreement**"), then the Company shall adjust the terms of the Warrants in a manner that is consistent with any adjustment made pursuant to Section 4.8 of the Original Warrant Agreement; provided, that in no event will any such adjustment under Section 4.8 of the Original Warrant Agreement be applied pursuant to this Section 4.8 in a manner that results in a number of shares of Common Stock being issued pursuant to this Warrant Agreement that, when taken together with the 1,000,000 shares of Common Stock sold under the Agreement, exceeds 19.99% of the total number of shares of Common Stock outstanding immediately prior to the execution of the Agreement.

5. TRANSFER AND EXCHANGE OF WARRANTS.

5.1 Transfer of Warrants. The Warrants may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than through a Permitted Transfer. The Warrants will not be listed on any quotation system or traded on any securities exchange. "**Permitted Transfer**" means a transfer of Warrants (a) upon death of a Registered Holder by will or intestacy; (b) pursuant to a court order; (c) by operation of law (including by consolidation or merger) or without consideration in connection with the dissolution, liquidation or termination of any corporation, limited liability company, partnership or other entity; or (d) in the case of Warrants held by the Registered Holder, by the Registered Holder to any affiliate of, or third party nominated by the Registered Holder, provided that the Registered Holder shall remain responsible for the obligations of the Registered Holder under the Side Letter and the Agreement; provided; however, that the permitted transferee must enter into a written agreement with the Company agreeing to be bound by the transfer restrictions in this Warrant Agreement. Any attempted sale, assignment, transfer, pledge, encumbrance, or other disposition, other than a Permitted Transfer, shall be void.

5.2 Registration of Transfer. The Company shall register the Permitted Transfer, from time to time, of any outstanding Warrant upon surrender of such Warrant for transfer, and, if in the form of a physical certificate, properly endorsed with signatures properly guaranteed and accompanied by appropriate instructions for transfer. Upon any such Permitted Transfer, a new Warrant representing an equal aggregate number of Warrants shall be issued and the old Warrant shall be cancelled by the Company.

5.3 Procedure for Surrender of Warrants. Warrants may be surrendered to the Company, together with a written request for exchange or Permitted Transfer, and thereupon the Company shall issue in exchange therefor one or more new Warrants as requested by the Registered Holder of the Warrants so surrendered, representing an equal aggregate number of Warrants.

5.4 Service Charges. No service charge shall be made for any exchange or registration of transfer of Warrants.

6. OTHER PROVISIONS RELATING TO RIGHTS OF HOLDERS OF WARRANTS.

6.1 No Rights as Stockholder. A Warrant does not entitle the Registered Holder thereof to any of the rights of a stockholder of the Company, including, without limitation, the right to receive dividends, or other distributions, exercise any preemptive rights to vote or to consent or to receive notice as stockholders in respect of the meetings of stockholders or the election of directors of the Company or any other matter.

6.2 Lost, Stolen, Mutilated, or Destroyed Warrants. If any Warrant is lost, stolen, mutilated, or destroyed, the Company may on such terms as to indemnity or otherwise as they may in their discretion impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination, tenor, and date as the Warrant so lost, stolen, mutilated, or destroyed. Any such new Warrant shall constitute a substitute contractual obligation of the Company, whether or not the allegedly lost, stolen, mutilated, or destroyed Warrant shall be at any time enforceable by anyone.

6.3 Reservation of Common Stock. The Company shall at all times reserve and keep available a number of its authorized but unissued shares of Common Stock that shall be sufficient to permit the exercise in full of all outstanding Warrants issued or issuable pursuant to this Warrant Agreement.

7. RESERVED.

8. MISCELLANEOUS PROVISIONS.

8.1 Successors. All the covenants and provisions of this Warrant Agreement by or for the benefit of the Company or the Registered Holder shall bind and inure to the benefit of their respective successors and assigns.

8.2 Notices. Any notice, statement or demand authorized by this Warrant Agreement to be given or made by the holder of any Warrant to or on the Company shall be sufficiently given when so delivered if by hand or overnight delivery or if sent by certified mail or private courier service within five (5) days after deposit of such notice, postage prepaid, addressed (until another address is filed in writing by the Company), as follows: :

Serina Therapeutics, Inc.
601 Genome Way, Suite 2001
Huntsville, Alabama 35806
Attention: Chief Financial Officer

With a copy to (which shall not constitute notice):
Bradley Arant Boult Cummings LLP
200 Clinton Ave. W., Ste. 900
Huntsville, AL 35801-4900
Attn: Scott Ludwig
Stephen Hinton

Any notice, statement or demand authorized by this Warrant Agreement to be given or made by the Company to Juvenescence shall be sufficiently given when so delivered if by hand or overnight delivery or if sent by certified mail or private courier service within five (5) days after deposit of such notice, postage prepaid, addressed (until another address is filed in writing by Juvenescence with the Company), as follows:

Juvenescence Limited
1st Floor
Viking House
St. Paul's Square
Ramsey
Isle of Man
IM8 1GB
Attention: David Gill, CFO

With a copy in each case to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA
Attn: Jacqueline Mercier 02210

8.3 Applicable Law. The validity, interpretation, and performance of this Warrant Agreement and of the Warrants shall be governed in all respects by the laws of the State of Delaware, without giving effect to conflicts of law principles that would result in the application of the substantive laws of another jurisdiction.

8.4 Persons Having Rights under this Warrant Agreement. Nothing in this Warrant Agreement shall be construed to confer upon, or give to, any person or corporation other than the parties hereto and the Registered Holders of the Warrants any right, remedy, or claim under or by reason of this Warrant Agreement or of any covenant, condition, stipulation, promise, or agreement hereof. All covenants, conditions, stipulations, promises, and agreements contained in this Warrant Agreement shall be for the sole and exclusive benefit of the parties hereto and their successors and assigns and of the Registered Holders of the Warrants.

8.5 Reserved.

8.6 Counterparts; Electronic Signatures. This Warrant Agreement may be executed in any number of original or facsimile counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument. A signature to this Warrant Agreement transmitted electronically shall have the same authority, effect and enforceability as a manual signature.

8.7 Effect of Headings. The section headings herein are for convenience only and are not part of this Warrant Agreement and shall not affect the interpretation thereof.

8.8 Amendments. This Warrant Agreement may be amended in a writing executed by the parties hereto.

8.9 Severability. This Warrant Agreement shall be deemed severable, and the invalidity or unenforceability of any term or provision hereof shall not affect the validity or enforceability of this Warrant Agreement or of any other term or provision hereof. Furthermore, in lieu of any such invalid or unenforceable term or provision, the parties hereto intend that there shall be added as a part of this Warrant Agreement a provision as similar in terms to such invalid or unenforceable provision as may be possible and be valid and enforceable.

Exhibit A Form of Incentive Warrant Certificate

Exhibit B Legend

IN WITNESS WHEREOF, the parties hereto have caused this Warrant Agreement to be duly executed as of the date first above written.

SERINA THERAPEUTICS, INC.

By: ____
Name: ____
Title: ____

JUVVENTURES (UK) LIMITED

By: ____
Name: ____
Title: ____

[Signature Page to Warrant Agreement]

EXHIBIT A

Form of Warrant Certificate

[FACE]

Number 1

Warrants

**THIS WARRANT SHALL BE VOID IF NOT EXERCISED PRIOR TO
THE EXPIRATION OF THE EXERCISE PERIOD PROVIDED FOR
IN THE WARRANT AGREEMENT DESCRIBED BELOW**

SERINA THERAPEUTICS, INC.
Incorporated Under the Laws of the State of Delaware

Warrant Certificate

This Warrant Certificate certifies that Juvenescence Limited, or registered assigns, is the registered holder of warrant(s) evidenced hereby (the “*Incentive Warrants*” and each, an “*Incentive Warrant*”) to purchase shares of common stock, \$0.0001 par value per share (“*Common Stock*”), of Serina Therapeutics, Inc., a Delaware corporation (the “*Company*”). Each Incentive Warrant entitles the holder, upon exercise during the period set forth in the Warrant Agreement referred to below, to receive from the Company that number of fully paid and non-assessable shares of Common Stock as set forth below, at the exercise price (the “*Exercise Price*”) as determined pursuant to the Warrant Agreement, payable in lawful money of the United States of America upon surrender of this Warrant Certificate and payment of the Exercise Price to the Company, subject to the conditions set forth herein and in the Warrant Agreement. Defined terms used in this Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Agreement.

Each whole Incentive Warrant is initially exercisable for one fully paid and non-assessable share of Common Stock. The number of shares of Common Stock issuable upon exercise of the Incentive Warrants is subject to adjustment upon the occurrence of certain events set forth in the Warrant Agreement.

The initial Exercise Price for any Incentive Warrant is equal to \$18.00 per Warrant. If, upon the exercise of Incentive Warrants, a holder would be entitled to receive fractional shares of Common Stock, the Company will round down to the nearest whole number the number of shares of Common Stock to be issued to the Incentive Warrant holder. The Exercise Price is subject to adjustment upon the occurrence of certain events set forth in the Warrant Agreement.

Subject to the conditions set forth in the Warrant Agreement, the Incentive Warrants may be exercised only during the applicable Exercise Period and to the extent not exercised by the end of such Exercise Period, such Incentive Warrants shall become void.

Reference is hereby made to the further provisions of this Warrant Certificate set forth on the reverse hereof and such further provisions shall for all purposes have the same effect as though fully set forth at this place.

This Warrant Certificate shall not be valid unless countersigned by the Company.

This Warrant Certificate shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to conflicts of laws principles thereof.

SERINA THERAPEUTICS, INC.

By: _____
Name:
Title:

Form of Incentive Warrant Certificate

[Reverse]

The Incentive Warrants evidenced by this Warrant Certificate are part of a duly authorized issue of Warrants entitling the holder on exercise to receive shares of Common Stock and are issued or to be issued pursuant to a Warrant Agreement dated as of January 31, 2025 (the “*Warrant Agreement*”), duly executed and delivered by the Company to JuvVentures (UK) Limited, a private limited company incorporated under the laws of England and Wales (“*Juvenescence*”), which Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to for a description of the rights, limitation of rights, obligations, duties and immunities thereunder of the Company and the holders (the words “*holders*” or “*holder*” meaning the Registered Holders or Registered Holder) of the Incentive Warrants. A copy of the Warrant Agreement may be obtained by the holder hereof upon written request to the Company. Defined terms used in this Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Agreement.

Incentive Warrants may be exercised at any time during the applicable Exercise Period set forth in the Warrant Agreement. The holder of Incentive Warrants evidenced by this Warrant Certificate may exercise them by surrendering this Warrant Certificate, with the form of election to purchase set forth hereon properly completed and executed, together with payment of the Exercise Price as specified in the Warrant Agreement to the Company. In the event that upon any exercise of Incentive Warrants evidenced hereby the number of Incentive Warrants exercised shall be less than the total number of Incentive Warrants evidenced hereby, there shall be issued to the holder hereof or his, her or its assignee, a new Warrant Certificate evidencing the number of Incentive Warrants not exercised.

The Warrant Agreement provides that upon the occurrence of certain events the number of shares of Common Stock issuable upon exercise of the Incentive Warrants set forth on the face hereof may, subject to certain conditions, be adjusted. If, upon exercise of an Incentive Warrant, the holder thereof would be entitled to receive a fractional interest in a share of Common Stock, the Company shall, upon exercise, round down to the nearest whole number of shares of Common Stock to be issued to the holder of the Incentive Warrant.

Warrant Certificates, when surrendered to the Company by the Registered Holder thereof in person or by legal representative or attorney duly authorized in writing, may be exchanged, in the manner and subject to the limitations provided in the Warrant Agreement, but without payment of any service charge, for another Warrant Certificate or Warrant Certificates of like tenor evidencing in the aggregate a like number of Incentive Warrants.

Upon due presentation for registration of transfer of this Warrant Certificate to the Company, a new Warrant Certificate or Warrant Certificates of like tenor and evidencing in the aggregate a like number of Incentive Warrants shall be issued to the transferee(s) in exchange for this Warrant Certificate, subject to the limitations provided in the Warrant Agreement, without charge except for any tax or other governmental charge imposed in connection therewith.

The Company may deem and treat the Registered Holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, of any distribution to the holder(s) hereof, and for all other purposes, and the Company shall not be affected by any notice to the contrary. Neither the Warrants nor this Warrant Certificate entitles any holder hereof to any rights of a stockholder of the Company.

Election to Purchase

(To Be Executed Upon Exercise of Warrant)

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, to receive shares of Common Stock and herewith tenders payment for such shares of Common Stock to the order of Serina Therapeutics, Inc. (the "**Company**") in the amount of \$_____ in accordance with the terms hereof. The undersigned requests that a certificate for shares of Common Stock be registered in the name of _____, whose address is _____, and that such shares of Common Stock be delivered to _____ whose address is _____. If said number shares of Common Stock is less than all of shares of Common Stock purchasable hereunder, the undersigned requests that a new Warrant Certificate representing the remaining balance of such shares of Common Stock be registered in the name of _____, whose address is _____ and that such Warrant Certificate be delivered to _____, whose address is _____.

[Signature Page Follows]

Date: , 20

(Signature)

(Address)

(Tax Identification Number)

EXHIBIT B

LEGEND

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE SOLD OR TRANSFERRED EXCEPT TO A PERMITTED TRANSFEREE (AS DEFINED IN SECTION 5 OF THE WARRANT AGREEMENT) WHO AGREES IN WRITING WITH THE COMPANY TO BE SUBJECT TO SUCH TRANSFER RESTRICTIONS.”

LIST OF SUBSIDIARIES

Subsidiary	Ownership	Country
Serina Therapeutics (AL), Inc.	100%	USA
Serina Therapeutics Australia Pty Ltd	100%	AUS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Serina Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Serina Therapeutics, Inc. (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' (deficit) equity, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the 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 cash flows for the years then ended, 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 financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has losses from operations, negative operating cash flows, accumulated deficit, and additional capital needs. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Frazier & Deeter, LLC

We have served as the Company's auditor since 2021.
Tampa, Florida
March 25, 2026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on the Forms S-8 (No. 333-281769 and No. 333-280250) of Serina Therapeutics, Inc. and subsidiaries (the “Company”) of our report dated March 24, 2025, with respect to the consolidated financial statements as of and for the years ended December 31, 2025 and 2024, of the Company which are part of this Annual Report on Form 10-K.

/s/ Frazier & Deeter, LLC

Tampa, Florida
March 25, 2026

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steve Ledger, certify that:

1. I have reviewed this annual report on Form 10-K of Serina 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 Rule 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 periodic 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 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 25, 2026

/s/ Steve Ledger

Steve Ledger
Chief Executive Officer

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Gregory S. Curhan, certify that:

1. I have reviewed this annual report on Form 10-K of Serina 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 Rule 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 periodic 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 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 25, 2026

/s/ Gregory S. Curhan

Gregory S. Curhan
Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Serina Therapeutics, Inc. (the “Company”) for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Steve Ledger, Chief Executive Officer, and Gregory S. Curhan, Chief Financial Officer, of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of our respective knowledge:

1. 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.

Date: March 25, 2026

/s/ Steve Ledger

Steve Ledger
Chief Executive Officer

/s/ Gregory S. Curhan

Gregory S. Curhan
Chief Financial Officer