2025 Annual Report

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2025

or

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

For the transition period from to
Commission File Number: 001-40060

LONGEVERON INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-2174146**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
1951 NW 7th Avenue, Suite 520 Miami, Florida	**33136**
(Address of Principal Executive Offices)	(Zip Code)

(305) 909-0840
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Class A common stock, par value $0.001 per share	**LGVN**	**The Nasdaq Capital Market**

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was approximately $16,492,155 as of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter).

As of March 9, 2026, the registrant had 21,783,749 shares of Class A common stock, $0.001 par value per share, and 1,484,005 shares of Class B common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE. None

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

In this document, the terms "Longeveron," "Company," "Registrant," "we," "us," and "our" refer to Longeveron Inc. We have no subsidiaries.

This Annual Report on Form 10-K (this "10-K") contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that reflect our current expectations about our future results, performance, prospects and opportunities. Such forward-looking statements can involve substantial risks and uncertainties. All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Factors that could cause actual results to differ materially from those expressed or implied in any forward-looking statements contained in this 10-K include, but are not limited to, statements about:

- our cash position and need to raise additional capital, the difficulties we may face in obtaining access to capital, and the dilutive impact it may have on our investors;
- our financial performance, and ability to continue as a going concern;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the ability of our clinical trials to demonstrate safety and efficacy of our investigational product candidates, and other positive results;
- the timing and focus of our ongoing and future preclinical studies and clinical trials, and the reporting of data from those studies and trials;
- the size of the market opportunity for certain of our investigational product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our ability to scale production and commercialize the investigational product candidate for certain indications;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our investigational product candidates;
- our ability to obtain and maintain regulatory approval of our investigational product candidates in the U.S. and other jurisdictions;
- our plans relating to the further development of our investigational product candidates, including additional disease states or indications we may pursue;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available and our ability to avoid infringing the intellectual property rights of others;
- the need to hire additional personnel and our ability to attract and retain such personnel; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, circumstances or otherwise occurring after the date this 10-K is filed.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

PART I

Item 1. Business

Introduction and Overview

We are a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. Our lead investigational product candidate is laromestrocel, also referred to as Lomecel-B®.

Laromestrocel is a proprietary, scalable, allogeneic cellular therapy that has multiple potential modes of action that include pro-vascular, pro-regenerative, and anti-inflammatory mechanisms that collectively appear to promote tissue repair and healing. Laromestrocel possesses broad potential applications across a spectrum of disease areas. Our mission is to continue to advance the development and regulatory approval of laromestrocel in order to make it available for patients who may need it.

Since our founding in 2014, we have focused the majority of our time and resources on the following: organizing and staffing our company, building, staffing and equipping a current good manufacturing practice ("cGMP") manufacturing facility with research and development labs, business planning, raising capital, establishing and maintaining our intellectual property portfolio, generating clinical safety and efficacy data in our selected disease conditions and indications, and developing and expanding our manufacturing processes and capabilities to support both internal and external development programs.

We manufacture our own investigational product candidates for early-phase clinical trials and have initiated enhancements to our Chemistry, Manufacturing and Controls ("CMC") infrastructure to support potential future Biologics License Application ("BLA") submissions. These efforts include planning for process and analytical method validation as well as commercial production readiness. As part of our ongoing preparations for a potential BLA submission for our lead investigational product candidate for Hypoplastic Left Heart Syndrome ("HLHS"), we have made a strategic decision to pursue commercial manufacturing through a third-party contract development and manufacturing organization ("CDMO"), rather than renovating our existing Miami facility for commercial-scale production. This decision was based on a comprehensive evaluation of multiple factors, including cost, timeline feasibility, and scalability. We believe this approach offers a more cost-effective and timely path to support our potential BLA submission and commercial launch. Our Miami manufacturing facility, which includes eight clean rooms, two research and development laboratories, and warehouse and storage space, will continue to support clinical development, research and early-phase manufacturing for our current and future clinical trials. We have supply contracts with multiple third parties for fresh bone marrow, which we use to produce our investigational product candidate for clinical testing and research and development. From time to time, we enter into contract development and manufacturing contracts or arrangements with third parties who seek to utilize our product development capabilities.

Operational Overview

We are currently in clinical development of a single investigational product candidate, laromestrocel, for four potential indications: HLHS, Alzheimer's disease ("AD"), Pediatric Dilated Cardiomyopathy ("pediatric DCM"), and Aging-related Frailty.

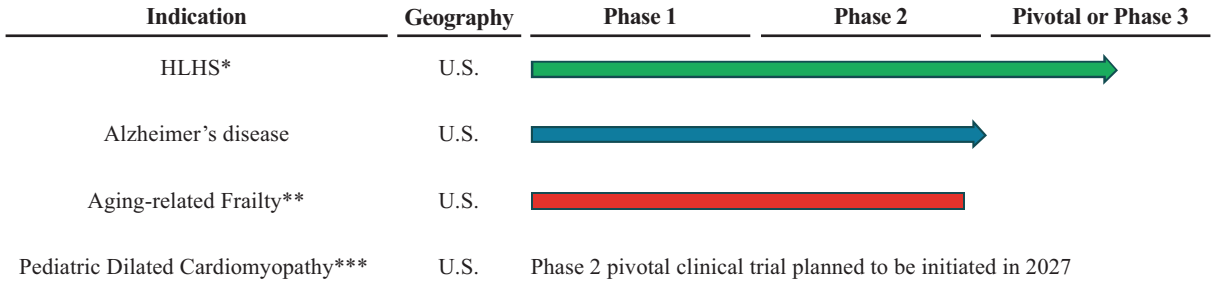

Figure 1: Laromestrocel clinical development pipeline

* Pivotal Phase 2b ELPIS II study; enrollment completed June 24, 2025

** Not currently active

*** We plan to conduct a single pivotal Phase 2 registrational clinical trial in accordance with the Investigational New Drug ("IND") application which became effective in July 2025.

As of December 2025, we have completed five U.S. clinical studies of laromestrocel: ELPIS I Phase 1 (HLHS), Phase 1 and "CLEAR MIND Trial", Phase 2a (AD), Phase 1/2 and Phase 2b Aging-related Frailty. We currently have one fully enrolled, ongoing clinical trial: ELPIS II Phase 2b (HLHS). Additionally, we sponsor a registry in The Bahamas under the approval and authority of the National Stem Cell Ethics Committee, now known as the National Longevity and Regenerative Therapy Ethics Review Committee. The Bahamas Registry Trial may administer laromestrocel to eligible participants at private clinics in Nassau, Bahamas for a variety of indications. While laromestrocel is considered an investigational product in The Bahamas, under the approval terms from the National Stem Cell Ethics Committee, we are permitted to charge a fee to participate in the Registry Trial.

Our current objective is to forge strategic collaborations and/or partnerships for the advancement of laromestrocel in all four potential indications.

Hypoplastic Left Heart Syndrome (HLHS)

HLHS is a rare congenital heart condition affecting approximately 1,000 newborns in the U.S. annually. HLHS is a birth defect that affects normal blood flow through the heart. As the baby develops during pregnancy, the left side of the heart does not form correctly so that babies are born with an underdeveloped or absent left ventricle. It is one type of congenital heart defect present at birth. Because a baby with this defect needs surgery or other procedures soon after birth, HLHS is considered a critical congenital heart defect. To prevent certain death shortly after birth, these babies undergo a series of three heart surgeries (staged surgical palliation) that reconfigures the single right ventricle to support systemic circulation. Despite these life-saving surgeries, HLHS patients nevertheless still have high early mortality and morbidity rates due primarily to heart failure. We are exploring the possibility that laromestrocel, when administered directly to the myocardium of affected infants, can improve outcomes in this devastating rare pediatric disease.

The FDA granted Rare Pediatric Disease Designation ("RPD") for laromestrocel for the treatment of HLHS (November 8, 2021), Orphan Drug Designation ("ODD") (December 2, 2021), and Fast Track Designation (August 24, 2022). We are currently conducting an ongoing Phase 2b clinical trial (ELPIS II) under FDA IND 17677. ELPIS II is a multi-center, randomized, double-blind, controlled clinical trial designed to evaluate laromestrocel as an adjunct therapy to the standard-of-care second-stage HLHS heart reconstructive surgery which is typically performed at 4-6 months after birth. The primary objective is to evaluate change in right ventricular ejection fraction after laromestrocel treatment versus standard-of-care surgery alone (40 subjects total: 20 per arm).

ELPIS II is a next-step trial to our completed 10-patient open-label Phase 1 trial (ELPIS I) under the same IND. ELPIS I trial was designed to evaluate the safety and tolerability of laromestrocel as an adjunct to the second-stage HLHS surgery, and to obtain preliminary evidence of laromestrocel effect to support a next-phase trial. The primary safety endpoint was met: no major adverse cardiac events ("MACE") or treatment-related infections during the first month post-treatment, and no triggering of stopping rules. Furthermore, fluid-based and imaging biomarker data supported multiple potentially relevant mechanisms-of-action of laromestrocel, and the potential to improve post-surgical heart function.

In January 2026, we announced that the FDA has granted us a Type C meeting at the end of March 2026 to prepare for the anticipated third quarter 2026 data readout of ELPIS II.

We have filed patent applications relating to the administration of laromestrocel for treating HLHS in Australia, The Bahamas, Canada, China, the European Patent Office, Japan, Hong Kong, South Korea, Taiwan, and the United States.

Alzheimer's Disease (AD)

AD, a devastating neurologic disease leading to cognitive decline, currently has very limited therapeutic options. An estimated 6.7 million Americans aged 65 and older have AD, and this number is projected to more than double by 2060. In September 2023, we completed our Phase 2a AD clinical trial, known as the CLEAR MIND trial. This trial

enrolled patients with mild AD and was designed as a randomized, double-blind, placebo-controlled study across ten U.S. centers. Our primary objective was to assess safety, and preliminary efficacy for three distinct laromestrocel dosing regimens against placebo.

The study demonstrated positive results. The safety profile of laromestrocel was safe and well tolerated when administered as single or multiple doses, with no incidence of hypersensitivity or infusion-related reactions. In addition, there were no cases of amyloid-related imaging abnormalities (ARIA). With regard to efficacy, laromestrocel showed slowing/prevention of disease worsening relative to placebo. The unadjusted p-values for a several secondary efficacy endpoint composite AD score ("CADS") for both the low-dose laromestrocel group and the pooled treatment groups compared to placebo suggested significance, indicating potential signals of efficacy. Other doses also indicated promising results in slowing/prevention of disease worsening.

Additionally, an improvement versus placebo was observed in the Montreal Cognitive Assessment ("MoCA") and in the activity of daily living observed by a caregiver and measured by Alzheimer's disease Cooperative Study Activities of Daily Living ("ADCS-ADL") with unadjusted p-values suggestive of significance. The study indicated potential preservation of the brain volumes in some but not all AD related areas of the brain 39 weeks after treatment commenced. Brain magnetic resonance imaging ("MRI") results demonstrated a 48% reduction in whole brain volume loss, 62% reduction in hippocampal volume loss, and potential improvement in neuroinflammation in some but not all brain regions via diffusion tensor imaging (DTI).

Based on these results, in July 2024, the FDA granted Regenerative Medicine Advanced Therapy ("RMAT") Designation and Fast Track designation to laromestrocel for the treatment of mild AD.

We believe laromestrocel is the only investigational product candidate to be granted RMAT designation for mild AD to date. In March 2025, Longeveron announced a positive Type B Meeting with the FDA supporting the advancement of laromestrocel as a potential treatment for mild AD. As a result of the Type B meeting, we reached foundational alignment with the FDA on the overall study design for a proposed single, pivotal, seamless adaptive Phase 2/3 clinical trial, including proposed AD patient population, proposed placebo control, laromestrocel dose selection and frequency, trial duration, and trial endpoints. To accelerate the pathway to potential approval of laromestrocel for the treatment of mild AD, the FDA agreed to consider a BLA based on positive interim trial results from the planned single study.

We have filed patent applications relating to the treatment of AD using laromestrocel in Australia, The Bahamas, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, New Zealand, South Korea, Singapore, South Africa, and the United States. We have also filed another family of patent applications relating to improving Brain Architecture in Alzheimer's disease using laromestrocel in The Bahamas, Taiwan, in addition to an application under the Patent Cooperation Treaty (PCT).

Aging-related Frailty

Improvement of the quality of life for the aging population is one of the strategic directions of the Company. Life expectancy has substantially increased over the past century due to medical and public health advancements. However, this longevity increase has not been paralleled by healthspan — the period of time one can expect to live in relatively good health and independence. For many developed and developing countries, health span lags life-expectancy by over a decade. This has placed tremendous strain on healthcare systems in the management of aging-related ailments and presents additional socioeconomic consequences due to patient decreased independence and quality-of-life. Since these strains continue to increase with demographic shifts towards an increasingly older population, improving health span has become a priority for health agencies, such as the National Institute on Aging ("NIA") of the National Institutes of Health ("NIH"), the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA"), and the European Medicines Agency ("EMA"). As we age, we experience a decline in our own stem cells, a decrease in immune system function (known as "immunosenescence"), diminished blood vessel functioning, chronic inflammation (known as "inflammaging"), and other aging-related alterations that affect biological functioning. In April 2024, we discontinued our clinical trial in Japan to evaluate laromestrocel for Aging-related Frailty. We plan to continue enrolling patients on the Frailty and Cognitive Impairment registry trials in The Bahamas and also plan to launch an Osteoarthritis registry trial.

Pediatric Dilated Cardiomyopathy (DCM)

DCM is a rare and life-threatening cardiovascular condition with unmet medical needs. Pediatric cardiomyopathies affect at least 100,000 children worldwide. DCM is the most common form of cardiomyopathy in children. About 50 to 60 percent of all pediatric cardiomyopathy cases are diagnosed as dilated. DCM is characterized by dilation and impaired systolic function of the left ventricle or both ventricles, typically in the absence of ischemia, abnormal loading conditions, or physiologic insult (e.g., sepsis). Diagnostic criteria for DCM include reduced measures of ventricular function combined with increased ventricular volumes adjusted for body size on cardiac imaging (left ventricular end-diastolic diameter (LVEDD) and left ventricular end-systolic diameter (LVESD) z-scores > 2). Treatments for DCM aim to ameliorate symptoms, reduce progression of disease, and prevent life-threatening arrhythmias. Treatment for DCM remains a complex challenge, marked by several limitations.

Clinical data to date with laromestrocel (a MSC therapy) indicates an acceptable safety profile in various disease indications administered via either IV or intramyocardial injection. Additionally, the safety profile from MSC therapies in general has been acceptable, supported by the literature review showing that MSC therapy has been evaluated in over one thousand clinical trials globally, with a favorable safety profile across numerous disease indications. DCM is associated with the loss of cardiomyocytes and with the replacement of lost cardiomyocytes by noncontractile fibrous tissue. Results from preclinical and clinical trials highlight the potential of MSC therapy to promote cardiomyogenesis, reduce inflammation and fibrosis, and support neovascularization. In adults with both ischemic cardiomyopathy and nonischemic dilated cardiomyopathy (DCM), MSC therapies have demonstrated improved LV function, functional status, and quality of life (QoL). Pediatric patients with DCM may be ideal candidates for MSC therapy because their hearts, including cardiomyocytes and progenitor cells, are more responsive to the signals from transplanted stem cells. Cell therapies have shown positive outcomes in DCM and other conditions, but further research is needed to confirm long-term safety and efficacy.

Our IND application for laromestrocel as a potential treatment for pediatric DCM became effective in July 2025. This IND provides for moving directly to a single pivotal Phase 2 registrational clinical trial in 2027, with planning and preparation beginning in 2026.

Summary of Clinical Development Strategy

Our core strategy is to become a world-leading regenerative medicine company through the development, approval, and commercialization of novel cell therapy products for unmet medical needs, with a near-term focus on HLHS. Key elements are as follows.

- Execution of ELPIS II to measure the efficacy of laromestrocel in HLHS. This trial is ongoing and is being conducted in collaboration with the National Heart, Lung, and Blood Institute (“NHLBI”) through grants from the NIH. As announced on June 24, 2025, the trial has reached full enrollment and we anticipate top-line trial results for ELPIS II in the third quarter of 2026. If the current ELPIS II trial in HLHS is successful, we believe the timing would be optimal to seek a potential BLA filing with the FDA in 2027 and commercialization partner.
- Continue to pursue the therapeutic potential of laromestrocel in mild AD. Our Phase 2a trial, CLEAR MIND Trial, met its primary safety endpoint across all treatment groups, with no safety concerns identified. The trial demonstrated nominal statistical significance on the secondary CADS composite endpoint, suggesting a potential benefit of laromestrocel compared with placebo in maintaining cognitive function and slowing brain structural decline. Specifically, MRI analyses indicated that patients treated with laromestrocel experienced a slowing of whole-brain volume loss and preservation of key brain regions, including left hippocampal volume, relative to placebo. These findings are hypothesis-generating and support further investigation of laromestrocel in mild AD. We plan to continue in-depth analyses of the data to refine our clinical development strategy. Our overarching objective is to advance laromestrocel through strategic collaborations and partnerships, with the goal of addressing the significant unmet medical need in AD.
- Preparation and initiation of a Phase 2 pivotal registrational clinical trial for pediatric DCM in 2027. Our IND application for laromestrocel as a potential treatment for pediatric DCM became effective in July 2025. If this trial is successful, we would then seek to partner the program for further development and potential commercialization.

- Expand our manufacturing capabilities. We operate a cGMP-compliant manufacturing facility and produce our own investigational product candidates for early-phase testing. As part of our HLHS commercialization strategy, we plan to utilize a CDMO for commercial-scale production, while continuing to leverage our Miami GMP facility for early-phase clinical supply, process development, and other supporting manufacturing activities for our early-phase clinical trials. We intend to continue to improve and expand our capabilities with the goal of achieving cost-effective manufacturing that may potentially satisfy supply for clinical trials product and certain CDMO contractual obligations.
- Advance BLA-enabling CMC activities, including process and analytical method validation planning and commercial production planning including technology transfer and commercial production readiness activities in support of third-party manufacturing.
- Collaborative arrangements and out-licensing opportunities. We will be opportunistic and consider entering into co-development, out-licensing, or other collaboration agreements for the purpose of eventually commercializing laromestrocel and other products domestically and internationally if appropriate approvals are obtained.
- Investigational product candidate development pipeline through internal research and development, and in-licensing. Through our research and development program, and through strategic in-licensing agreements, or other business development arrangements, we intend to actively explore promising potential additions to our pipeline.
- Continue to expand our intellectual property portfolio. Our intellectual property is vitally important to our business strategy, and we have taken and continue to take significant steps to develop this property and protect its value. Results from our ongoing research and development efforts are intended to add to our existing intellectual property portfolio.

Manufacturing

The manufacture and delivery of cell therapy products to patients involves complex, integrated processes. Commercial success in this area requires manufacturing processes that are reliable, scalable, and economical. We currently operate a manufacturing facility in Miami, Florida, which supplies laromestrocel for our early-phase clinical trials and also serves as our corporate headquarters. We have devoted and plan to continue devoting significant resources to optimization of process development and manufacturing to reduce per-unit manufacturing costs and to support efficient scale-up of production through a combination of internal capabilities and third-party manufacturing arrangements upon approval of any of our investigational product candidates in a particular country.

Our current good manufacturing practices ("cGMP") facility went online in early 2017 and consists of 4,150 ft^2 (385.5 m^2) with approximately 3,000 ft^2 (279 m^2) of cGMP space comprised of eight International Organization for Standardization ("ISO") 7 cleanrooms, and ISO 8 ancillary areas and 1,150 ft^2 (107 m^2) of warehouse, research and development and Quality Control space, including two research and development laboratories. The cGMP cleanrooms are used exclusively for the manufacture of human cellular therapy investigational product candidates for use in early-phase clinical trials. The facility is in compliance with FDA regulations in the Code of Federal Regulations 21, Parts 210 and 211.

Laromestrocel consists of human allogeneic (donor) bone-marrow derived mesenchymal stem cells ("MSC") as the active ingredient. These cells undergo culture-expansion using proprietary processes, and are then formulated, packaged and stored frozen (cryopreserved) until shortly before use. Fresh bone marrow is procured from established, licensed U.S.-based third-party tissue suppliers, which harvest the tissue from young, healthy consenting adult donors. Laromestrocel is produced using processes that FDA has reviewed and authorized as part of our INDs. We currently have multiple suppliers for GMP-grade bone marrow. These suppliers provide adequate bone marrow for our current and anticipated needs; however, if one or more suppliers were to no longer provide bone marrow, alternate suppliers would be needed or our ability to produce laromestrocel in the future could be impacted.

Technology Capabilities

From the commencement of operations in 2014, we recognized the potential for a cellular therapy to be a novel investigational product candidate in our chosen indications. We have assembled a team of experts and proprietary technologies that we believe enables us to take a systematic approach to rapidly develop improved cell therapies. We believe having established manufacturing capabilities and operations within the U.S. early in the development of our investigational product candidates is a competitive advantage. Over time, as needed and appropriate, we expect to support commercialization through CDMO partners while continuing to leverage our internal manufacturing capabilities for early-phase clinical supply and process and analytical development. We believe that anticipated future clinical and commercial demand for laromestrocel and new pipeline programs can be met, as our process has been designed to meet these demands as milestones are achieved. We believe our scalable robust manufacturing process, along with our proprietary technologies and our industry experienced team, would be challenging and costly for potential competitors to replicate.

Contract Development and Manufacturing Services

We produce all of our investigational product candidates in the ISO 7 cleanrooms of our cGMP facility to satisfy our ongoing clinical studies and The Bahamas Registry Trial. As a revenue-generating opportunity, occasionally we utilize excess capacity, when available, to provide contract manufacturing and development services to third parties; however, our business development activity is limited in this area.

Manufacturing Services Agreement

On February 21, 2024, the Company entered into a five-year Supply Agreement with a third-party biotechnology company developing multiple, novel secretomes ("Secretome") to address a spectrum of diseases driven by pathological processes, to manufacture, test, release, and supply Secretome with cardiac stem cells (the "Product") to be used in Phase 1 and Phase 2 clinical trials (the "Secretome Agreement"). The Company received an initial start-up payment upon signing and bills Secretome on a variable fee basis for quality control, in process, release, and stability testing service items. Secretome also pays a monthly manufacturing suite reservation fee and hourly fee for project management services. During 2025, activities under the Secretome Agreement substantially decreased, and the Company is now only performing limited stability and other contract testing. No additional manufacturing or development activities are planned, and the Company does not anticipate significant future revenue under the Secretome Agreement.

Commercialization

We currently have no established sales, marketing or product distribution infrastructure. In order to commercialize any of our investigational product candidates if approved for commercial sale, we will need a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third parties that have sales and marketing experience. As we move our investigational product candidates through development toward regulatory approval, we plan to evaluate several options for each investigational product candidate's commercialization strategy. These options include further building an internal sales force, entering into a joint marketing collaboration with another pharmaceutical or biotechnology company, or out-licensing any future approved product to another pharmaceutical or biotechnology company. All such commercialization will be undertaken in accordance with applicable law.

Competition

The field of regenerative medicine, which includes gene therapies, cell therapies (such as laromestrocel), and tissue-engineered products, is broadly defined as "products intended to repair, replace or regenerate organs, tissues, cells, genes, and metabolic processes in the body," per the Alliance for Regenerative Medicine ("ARM"), an international advocacy organization. Regenerative medicine companies number in the thousands worldwide as of February 2026.

In the following table is a general, non-comprehensive list of cellular therapy companies that we believe could be considered our primary competition, either because they also develop MSCs as their primary mode of action, albeit for different indications in most cases, or on the basis that these companies are addressing the same indications as Longeveron.

ARDS = Acute Respiratory Distress Syndrome; aGvHD = Acute graft versus host disease; GvHD = Graft-versus-host-disease; ALS = Amyotrophic lateral sclerosis; MS = Multiple sclerosis; BPD = Bronchopulmonary dysplasia; CLI = Critical limb ischemia; CMD = Coronary microvascular disease; ARS = Acute radiation syndrome.

Company	Corporate Headquarters	Clinical stage pipeline indications
BioCardia	USA	Ischemic heart failure; Chronic Myocardial Ischemia
BlueRock Therapeutics	USA	Parkinson's disease
BrainStorm Cell Therapeutics	Israel	Alzheimer's disease; MS; Lateral Sclerosis; Parkinson's disease
CellProthera	France/USA	Acute Myocardial Infarction
CorestemChemon	South Korea	ALS (commercial in South Korea); Lupus
Cynata Therapeutics	Australia	Graft-versus-host-disease; ARDS
Healios KK	Japan	Ischemic Stroke; ARDS
Kadimastem	Israel	Alzheimer's disease; MS; Diabetes
Medipost	South Korea	Osteoarthritis; Bronchopulmonary Dysplasia
Mesoblast	Australia	Heart failure; HLHS; aGvHD; ARDS; Crohn's Disease (one product approved for aGvHD)
SanBio Co Ltd	Japan	Ischemic stroke; Brain Injury
Stemedica Cell Technologies	USA	Ischemic Stroke; COVID-19/ARDS; Alzheimer's disease; Cutaneous Photoaging IV; Heart failure; AMI; Traumatic Brain Injury

Mesoblast

On December 18, 2024, the FDA approved Ryoncil (remestemcel-L-rknd), an allogeneic (donor) bone marrow-derived MSC therapy indicated for the treatment of steroid-refractory acute graft-versus-host disease (SR-aGVHD) in pediatric patients two months of age and older. Ryoncil is the first FDA-approved MSC therapy. It contains MSCs, which are a type of cell that can have various roles in the body and can differentiate into multiple other types of cells. These MSCs are isolated from the bone marrow of healthy adult human donors.

We believe the FDA's approval of the Mesoblast product Ryoncil represents a positive development for Longeveron, as it belongs to the same class of cell therapy as laromestrocel.

Intellectual Property

We seek to protect our 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, acquired from third parties, or licensed from third parties. We also intend to seek and rely on any statutory or regulatory protections, including FDA's expedited review program, data exclusivity, market exclusivity and patent term extensions where available. Longeveron has applied for USAN approval of "laromestrocel."

Longeveron received notice from the World Health Organization ("WHO") that the name "laromestrocel" for our Lomecel-B® product has been adopted by the WHO and published in the International Nonproprietary Names (INN) list 132 on February 13, 2025.

We have a combination of Company-owned and in-licensed patents and patent applications related to cell-based therapy and its various uses. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and enforce and therefore provide us with only limited protection.

We expect to file additional patent applications in support of current and new investigational product candidates, as well as for process and manufacturing-related improvements or inventions, should these arise. These expected additional patent applications may be related to existing patent applications or may create new patent families. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our current and future investigational product candidates and the methods used to develop, manufacture, administer, and use them. Our commercial success will also depend on successfully defending our patents against third-party challenges and operating without infringing on the proprietary rights of others. We are aware of several

U.S. patents held by third parties covering potentially similar or related products, and their manufacture and use. Generally, conducting clinical trials and other acts relating to FDA approval are not considered acts of infringement in the U.S. If and when LOMECEL-B brand laromestrocel MSCs are approved by the FDA, third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. Our ability to deter and, if necessary, to stop third parties from making, using, selling, offering to sell or importing our investigational product candidates or products that are similar to our investigational product candidates depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We can neither be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our investigational product candidates, discovery programs and processes. Unpublished third-party patent applications may exist that would have an effect on our freedom to operate. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors-Risks Related to Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most jurisdictions where we file, including the U.S., the patent term is 20 years from the earliest effective filing date of a non-provisional patent application. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO"), in examining and granting a patent. Patent term in the U.S. may be shortened if a patent is subject to a terminal disclaimer over another patent. Delays on the part of a patentee may decrease patent term adjustment.

In the U.S., the term of a patent that covers an FDA-approved "active ingredient" or methods of its use may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch-Waxman Amendments, or the Biologics Price Competition and Innovation Act of 2009 permit a patent term extension of up to five years beyond the expiration of the statutory term of a patent, including any patent term adjustment to which the patent is entitled. The length of the patent term extension is related to the length of time the active ingredient or method is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our investigational product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions for any issued patents we may obtain in any jurisdiction where such patent term extensions are available. We are not assured that the applicable authorities, including the FDA in the U.S., will agree with our assessment of whether such extensions should be granted, and if granted, the length of those extensions. For more information regarding the risks related to our intellectual property, see "Risk Factors-Risks Related to Intellectual Property."

We may file patent applications directly with the USPTO as provisional applications. We may file U.S. non-provisional applications, direct foreign applications under the Paris Convention and the Agreement on Trade Related Aspects of Intellectual Property Rights, and Patent Cooperation Treaty ("PCT") applications. Those applications may claim the benefit of the priority date of one or more earlier filed applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application and to designate all of the PCT member states in which national or regional patent applications can later be pursued based on the PCT application.

For all patent applications, we determine claim strategy on a case-by-case basis. Advice of counsel and our business model and needs are considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We routinely reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes and compositions. Further, we may modify claims during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors. These include the volume and scope of the prior art, the novelty, non-obviousness, and utility of the invention, and the ability to satisfy the written description and enablement requirements of the patent laws. In addition, the coverage claimed in a patent application can be significantly narrowed before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future investigational product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will be issued as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from copying by competitors. Any patents that we hold may be challenged, circumvented, or invalidated by third parties. We cannot predict whether, in certain jurisdictions, a third-party will use a method confidentially that we later independently discover and patent, which may result in a limited grant to the third party of the ability to continue to practice that method despite our patent.

In addition to patent protection, we rely on trademark registration, trade secrets, know-how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contracts with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets indefinitely.

It is our standard practice to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except under specific circumstances. Our standard agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors, or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see "Risk Factors-Risks Related to Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific, and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies or our future products or processes, to obtain licenses or to cease certain activities. Our breach of any license agreement or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. If third parties file requests for inter partes review of our patents, then we may have to defend those patents in the USPTO. For more information, see "Risk Factors-Risks Related to Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or investigational product candidates.

Company-Owned Intellectual Property

MSCs as Vaccine Adjuvants and Methods for Using the Same. The claims within this family are currently directed to methods of enhancing the immune response to vaccination, which was one of the research objectives of our Phase 1/2 HERA Trial. This research is relevant to Aging-related Frailty subjects, who are particularly vulnerable to the effects of viral contagion, such as influenza or COVID-19, and who may be lacking in immunoprotection.

Certain claims address the ability to enhance a subject's immune response to a vaccine through the administration of a therapeutically effective amount of allogeneic MSCs in a subject that exhibits "inflammaging." See, e.g., USP 11975068, claim 1. In this family we have one issued patent in Australia and one issued patent in the United States. We have three pending applications in Japan, one pending application in the United States, one pending application in Australia, and one pending application in the European Patent Office. One European Patent Office application was granted and then validated in Switzerland, Germany, Spain, France, Great Britain, Italy, and Sweden. All of the patent applications are national or regional phase applications based on a Patent Cooperation Treaty ("PCT") application filed in February 2017 and claiming priority to a U.S. provisional application filed in February 2016. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in 2037. Longeveron has elected to take no further action and to allow to become abandoned, properties in this family in Canada, Hong Kong, Israel, Singapore, South Africa, South Korea, and New Zealand.

Methods of Using Human MSCs to Effect Cellular and Humoral Immunity. Certain claims in this family of patent applications relate to the ability for MSC therapy to improve the immune system function in patients with chronic systemic inflammation, a hallmark of frailty.

In this family we own pending applications in The Bahamas, Australia, Canada, China, Hong Kong (where there are three applications), the European Patent Office, South Korea, New Zealand (where there are three applications), Singapore, and the United States. Patents have issued in Australia, Canada, China, Taiwan, the United States, and Israel, two patents have issued in Japan, and a patent registration has been made in South Africa. With two exceptions (The Bahamas and Taiwan), all of the applications are national or regional phase applications based on a PCT application filed in November 2017 and claiming priority to a U.S. provisional application filed in November 2016. The application in The Bahamas and the patent in Taiwan claim priority to that same provisional application but were not filed using the PCT. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in 2037.

Treatment of Sexual Dysfunction and Improvement in Sexual Quality of Life. This application family is directed towards increasing libido and improving sexual function and satisfaction in a female patient through the use of allogeneic or autologous MSC therapy, whether derived from bone marrow, adipose tissue or induced pluripotent stem cells (iPSCs). In this family we own and we are continuing to prosecute or maintain applications in the United States and European Patent Office. We have one patent in Japan and one patent in the United States. We also own and are continuing to maintain a patent registration in The Bahamas. The U.S., Japanese, and European properties are a national or regional phase applications based on a PCT application filed on June 15, 2018 and claiming priority to a U.S. provisional application filed in June 2017. The registration in The Bahamas claims priority to that same provisional application but was not filed using the PCT. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in June 2038. Longeveron has elected to take no further action and to allow to become abandoned, properties in the family in Australia, Canada, China, Hong Kong, Israel, Korea, Singapore, South Africa, South Korea, Taiwan, and New Zealand.

Potency Assay. This application family is directed towards assessing potency of MSCs to produce anti-inflammatory cytokines in response to a pro-inflammatory stimulus. In this family we own pending applications in Australia, The Bahamas, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, New Zealand, the Republic of Korea, Singapore, South Africa, and the United States. These applications have a filing date in April 2021 and claim priority to a U.S. provisional application filed in April 2020. If issued and assuming that all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in April 2041.

Use of MSCs in Treatment of Juvenile Hypoplastic Left Heart Syndrome. This patent family is directed to treatment of HLHS with allogeneic MSCs. These applications share a common priority date of July 2021. National and regional phase applications based on pending PCT application have been filed in Australia, Canada, China, the European Patent Office, Japan, Hong Kong, South Korea, and the United States. Applications are also pending in Taiwan and The Bahamas. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in July 2042.

Administration of MSCs for Aging-related Frailty. This patent family relates to administration of MSCs to treat symptoms of Aging-related frailty. These applications share a common priority date of September 2021. National and regional phase applications based on the pending PCT application have been filed in Australia, Canada, China,

the European Patent Office, Hong Kong, Israel, Japan, New Zealand, South Korea, Singapore, and South Africa. We also own applications in Taiwan and The Bahamas. If issued, and assuming that all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in September 2042.

Treatment of Alzheimer's Disease with Allogeneic MSCs. This patent family relates to administration of MSCs to treat AD. We own pending patent applications in Australia, The Bahamas, South Korea, Singapore, South Africa, Israel, Canada, Hong Kong, New Zealand, China, Japan, the European Patent Office, and the United States. Those applications claim priority to three separate U.S. provisional applications, the earliest of which was filed in September 2020. If issued, and assuming that all maintenance and annuity fees are paid, patents arising from these applications are expected to expire in September 2041.

Improved Brain Architecture in Alzheimer's Disease with MSCs. This patent family relates to administration of MSCs to treat AD. We own pending patent applications in this family in Taiwan, The Bahamas, and the PCT. Those applications all claim priority to a United States provisional patent application filed on December 19, 2023. If the patent applications are allowed, any patents that issue are expected to expire on December 19, 2044.

Potency Assay. This patent family relates to alleviation of symptoms, for example of AD, by administration of allogeneic MSCs and evaluation of biomarkers. We own pending applications in this family in the Bahamas, Taiwan, and the PCT, along with two continuation-in-part applications in the United States. These applications all claim priority to a United States provisional patent application filed on March 21, 2024. If issued, and assuming that all maintenance and annuity fees are paid, patents arising from these applications are expected to expire on March 21, 2045.

License Agreements and Strategic Collaborations

The University of Miami ("UM")

On November 20, 2014, we entered into an Exclusive License Agreement with UM (the "UM License") for the use of certain Aging-related Frailty-related MSC technology rights developed by our Chief Science Officer, Dr. Joshua Hare, at UM. The UM License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how specifically related to the development of the culture-expanded MSCs for Aging-related Frailty, all standard operating procedures used to create the Human-induced pluripotent stem cell-derived mesenchymal stem cells ("IMSCs"), and all data supporting isolation, culture, expansion, processing, cryopreservation, and management of the IMSCs.

We are required to pay UM (i) a license issue fee of $5,000, (ii) a running royalty in an amount equal to three percent of annual net sales on products or services developed from the technology, payable on a country-by-country basis beginning on the date of first commercial sale through termination of the UM License Agreement, and which may be reduced to the extent we are required to pay royalties to a third party for the same product or process, (iii) escalating annual cash payments of up to $50,000, subject to offset. The agreement extends for up to 20 years from the last date a product or process is commercialized from the technology and was amended in 2017 to modify certain milestone completion dates as detailed below. In 2021 the license fee was increased by an additional $100,000, to defray patent costs. In addition, the Company issued 11,039 unregistered shares of Class A common stock to UM.

The milestone payment amendments shifted the triggering payments to three payments of $500,000, to be paid within six months of: (a) the completion of the first Phase 3 clinical trial of the products (based upon the final data unblinding); (b) the receipt by the Company of approval for the first new drug application ("NDA"), BLA, or other marketing or licensing application for the product; and (c) the first sale following product approval. "Approval" refers to product approval, licensure, or other marketing authorization by the U.S. FDA, or any successor agency. The amendments also provided for the Company's license of additional technology, to the extent not previously included in the UM License and granted the Company an exclusive option to obtain an exclusive license for (a) the HLHS IND with ckit+ cells; and (b) UMIP-438 titled "Method of Determining Responsiveness to Cell Therapy in Dilated Cardiomyopathy."

The additional technology that was licensed included a family of patent applications based on PCT Application No. PCT/US2015/060624, for "Substances and Methods for Treating Endothelial Dysfunction and Methods for Monitoring the Effectiveness of a Therapy in a Subject," with patents granted in South Korea, Brazil, and Europe (with validation in France, Germany, Italy, Spain, Sweden, Switzerland, and the United Kingdom), and a divisional application pending in Europe.

We have the right to terminate the UM License upon 60 days' prior written notice, and either party has the right to terminate upon a breach of the UM License. To date, the Company has made payments totaling $0.5 million to UM, and as of December 31, 2025, we accrued $7,500 in milestone fees payable to UM.

The Company also entered into an additional Exclusive License Agreement with UM, signed and effective as of July 18, 2024, for technology rights developed by our CSO at UM. This License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how, SOPs, data and other all other rights related to UMP-144, entitled "A method to derive GHRHR+ cardiomyogenic cells from pluripotent stem cells (PSCs) for therapeutic and pharmacologic applications". UM retained a non-exclusive, royalty-free, perpetual, irrevocable, worldwide right to practice, make, and use the Patent Rights or Technology for any non-profit purposes, including educational, and research purposes. Pursuant to the terms of the license agreement, Longeveron must pay to UM: (a) $5,000 within 30 days of the Effective Date; and (b) reimbursement of $21,307 within 90 days of the Effective Date for previously incurred patent expenses; and (c) an annual $10,000 fee which is both creditable against other royalty payments for the applicable license year and is waived so long as Company is current on annual fee payments in accordance with the Exclusive License Agreement entered into November 20, 2014 between Company and UM. In addition to those certain other royalty payments that would be due should the Company's sublicense of the technology result in revenue, Longeveron also agreed to the following additional milestones and payments: $150,000 upon completion of the first Phase 3 Clinical Trial; and $250,000 upon issuance of a biologics license application or new drug application based on the licensed technology. The Company has the right to terminate the new UM License for convenience upon 90 days' prior written notice, and both parties have additional termination rights for material breach of the agreement. To date, the Company has made payments totaling $5,000 to UM, and as of December 31, 2025, the Company had not yet accrued any milestone fees payable to UM.

CD271

On December 22, 2016, we entered into a worldwide exclusive license agreement with JMH MD Holdings, LLC ("JMHMD"), an affiliate entity of our Chief Science Officer, Dr. Joshua Hare, for the use of CD271 cellular therapy technology. We are required to pay JMHMD a running royalty in an amount equal to one percent of the annual net sales of the licensed product(s) used, leased, or sold by or for us by any sub-licensees, which amounts are payable on a country-by-country basis beginning on the date of first commercial sale and ending on the latter of expiration of the last to expire patent rights in such country or ten years from the first commercial sale in such country (provided that if all claims within the patent rights have expired or been finally deemed invalid then the royalty will be reduced by 50%), and which may also be reduced to the extent we are required to pay royalties to a third party for the same product or process. We are also required to pay an initial fee and, by the first day of each anniversary of the Agreement, starting with the second anniversary, a minimum royalty of ten thousand dollars. JMHMD also received an equity grant equal to one-half of one percent of the then outstanding units of the Company on a fully-diluted basis. If we sublicense the technology, we are also required to pay an amount equal to 10% of the net sales of the sub-licensees.

Under the agreement, the Company is required to use commercially reasonable efforts to achieve the following milestones: (i) submit an IND to FDA (or international equivalent) within one year of effective date of agreement, (ii) initiate a clinical trial utilizing bone marrow derived CD271+ Precursor Cells within three years of the effective date; provided, that any of the milestones may be extended for up to six months for a total of three times by notice and payment of a five thousand dollar extension fee. Failure to achieve these milestones within five years of the effective date triggers a right of termination by JMHMD. Otherwise, the agreement is to remain in effect until either the date all issued patents and filed patent applications have expired or been abandoned, or 20 years after the date of FDA approval of the last commercialized product or process arising from the patent rights whichever comes later. Further, each party has the right to terminate upon sixty days' prior written notice, or in the event of breach. If the Company sublicenses the technology, it is also required to pay an amount equal to 10% of the net sales of the sub-licensees.

To date, the Company has not incurred any royalty or sublicense related expense, but has paid $45,000 in license fees ($10,000 per year for 2021, 2020 and 2019) and for a $15,000 extension fee. In addition, the Company paid legal fees of approximately $27,000 and $30,000 for the years ended December 31, 2025 and 2024, respectively, in connection with the patent prosecution, issuance, and maintenance fees related to CD271+ technology.

In-licensed Patents and Applications

Bone Marrow Derived CD271+ Precursor Cells for Cardiac Repair. We have in-licensed the exclusive right to use CD271+ MSC precursors from bone marrow to treat certain aging-related conditions and diseases, such as frailty, Metabolic Syndrome, loss of muscle due to aging or frailty and neurocognitive disorders. That patent has issued in Australia, Brazil, Canada, China, Israel, Japan, South Korea, Mexico, New Zealand, Germany, Spain, France, the United Kingdom, Italy, Sweden, and Singapore. The patent application remains pending in the U.S. While method of use claims may relate to the use of CD271+ cells for cardiac repair, our license terms exclude our use of CD271+ cells for preventing and treating cardiovascular diseases or disorders, including congenital cardiovascular defects. Assuming that all maintenance and annuity fees are paid, patents in this family are expected to expire in August 2031.

Methods for Obtaining Cardiomyogenic Precursor Cells. We have in-licensed from the University of Miami the exclusive right (with limited non-exclusivity for educational, research, and non-profit uses reserved to the University) to certain methods for obtaining cardiomyogenic precursor cells. One licensed U.S. patent has issued, and one U.S. patent application is pending in the licensed family.

Methods for Monitoring Efficacy of Allogeneic MSC Therapy in a Subject (a/k/a Substances and Methods for Treating Endothelial Dysfunction and Methods for Monitoring the Effectiveness of a Therapy in a Subject). We have in-licensed from the University of Miami the exclusive right (with limited rights retained by the University) to certain methods for monitoring efficacy of allogeneic mesenchymal stem cell therapy. Patents have been granted in Brazil, South Korea, and Europe (with validation in France, Germany, Italy, Spain, Sweden, Switzerland, and the United Kingdom), with a divisional application pending in Europe.

Trademarks

We have registered trademarks or applied for registered trademarks for "Longeveron" in the following jurisdictions. We have phased out the registrations and applications for "LMSC" in favor of registrations for "LOMECEL-B". In some jurisdictions multiple registrations and/or applications exist so that multiple goods and/or services may be listed:

Territory	"LOMECEL-B®"	"Longeveron"
The Bahamas		Registered
Brazil		Registered
Canada		Registered
China		Registered
European Union		Registered
Hong Kong		Registered
India		Registered
Japan		Registered
South Korea		Registered
Morocco		Registered
Panama		Registered
Switzerland		Registered
Taiwan		Registered
U.S.	Reg. No. 8,005,125	Two allowed applications and one registration, Reg. No. 7,322,945
Vietnam		Registered

Government Regulation and Biologic Drug Approval

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. We believe that the FDA will regulate laromestrocel as a biologic drug (i.e., a biologic) through the BLA process under the jurisdiction of the Center for Biologics Evaluation and Research ("CBER").

U.S. Biologic Drug Development Process

In the U.S., biologics are regulated under two statutes: The Public Health Service Act ("PHS Act") and the federal Food, Drug, and Cosmetic Act ("FFDCA") and their implementing regulations. However, approval of only one application — typically either a BLA or an NDA — is required prior to marketing. Numerous FDA "Guidance Documents" and other materials address specific aspects of development for specific types of investigational product candidates (e.g., cells, tissues, gene therapies, or vaccines). The process of obtaining approval and complying with applicable statutes and regulations requires substantial time and financial resources. Failure to comply with the applicable U.S. requirements before, during, or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold on ongoing clinical trials, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a biologic may be marketed in the U.S. generally involves the following steps:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations;
- submission of an IND, which must become effective before human clinical trials may begin;
- review and approval by an independent institutional review board ("IRB") at each clinical site (or by one "commercial IRB") before each trial may be initiated;
- conduct adequate and well-controlled human clinical trials in accordance with current good clinical practice ("cGCP") requirements to establish the safety, purity, and potency (i.e., efficacy) of the proposed biologic for its intended use;
- submission of a BLA after completion of the required clinical trials and non clinical studies;
- review of the BLA by the FDA, which may include review by an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of clinical investigation sites and the manufacturing facility or facilities at which the biologic is produced;
- licensure of the manufacturing facility or facilities in connection with approval of the BLA, as required for biologic products under the Public Health Service Act; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the U.S.

The specific preclinical studies and clinical testing that are required for a BLA varies widely depending upon the specific type of investigational product candidate under development. Prior to beginning a human clinical trial with either a biologic or drug product candidate in the U.S., we must submit an IND that must become effective. The focus of an IND is the general investigational plan and protocol for the proposed clinical study. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls ("CMC") information; and any available human data or literature to support the use of the investigational product candidate. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical hold is lifted and the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. A clinical trial can also be placed on clinical hold once the study has begun.

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of qualified investigators in accordance with cGCPs, including that all research subjects provide their informed consent to participate. Clinical trials are conducted under protocols detailing, among other things, the

study objectives, safety monitoring, and effectiveness criteria. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development. Other submissions to an IND include protocol amendments, information amendments, IND safety reports and annual reports. Furthermore, an independent IRB for each clinical trial site (or a single "commercial IRB") must review and approve the protocol and informed consent form before the clinical trial may begin. The IRB also monitors the clinical trial until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some clinical trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee ("DMC"). A DMC authorizes whether or not a study may move forward at designated check points based on data and results from the trial. The DMC may halt the clinical trial based on an unacceptable safety risk or on other grounds, such as a failure to demonstrate efficacy. Related reporting requirements for the sponsor, clinical investigator, and/or IRB also include IND safety reports and updating clinical trial results in public registries (e.g., ClinicalTrials.gov).

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined. The size of these clinical trials will vary depending on the investigational product candidate and the size of the patient population:

- Phase 1: The investigational product candidate is initially introduced into healthy human subjects to test the safety, dosage tolerance, absorption, metabolism, distribution, excretion, side effects, and, if possible, early evidence of effectiveness. In the case of some investigational product candidates for severe or life-threatening diseases when the investigational product candidate may be too inherently toxic to ethically administer it to healthy volunteers, Phase 1 studies may instead be conducted in individuals who have the targeted disease or condition instead of healthy subjects.

- Phase 2: The investigational product candidate is administered to a limited population of individuals who have the specified disease or condition to evaluate safety, preliminary efficacy, optimal dosages and dosing schedule, possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 (i.e., pivotal) clinical trials.

- Phase 3: Phase 3 clinical trials are generally the largest studies conducted at multiple clinical trial sites. The investigational product candidate is administered to an expanded population that has the specified disease or condition to further evaluate dosage, provide statistically significant evidence of clinical efficacy and gain additional safety data. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product candidate and to provide an adequate basis for product approval.

Concurrent with clinical trials, sponsors usually complete additional animal studies, develop information about the chemical and physical characteristics of the biologic and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must consistently produce quality batches of the investigational product candidate. Furthermore, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final biologic. In addition, the sponsor must develop and test appropriate packaging and conduct stability studies to demonstrate that it does not undergo unacceptable deterioration over its shelf life.

During the development of a new biologic, sponsors are given opportunities to meet with the FDA. These meetings typically occur prior to submission of an IND (i.e., pre-IND meeting), at the end of Phase 2 (i.e., EOP2 meeting), and before a BLA is submitted (i.e., pre-BLA meeting). Meetings at other times may be requested and granted if, for example, an investigational product candidate has received a Fast Track or Breakthrough Therapy designation. These meetings provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use EOP2 meetings to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new biologic.

U.S. Review and Approval Process for Biologic Drugs

Assuming successful completion of all required testing, the sponsor submits a BLA containing the results of product development, preclinical and other non-clinical studies and clinical trials, descriptions of the manufacturing process, analytical testing, proposed labeling and other relevant information. The submission of a BLA is subject to the payment of a substantial application fee under the Prescription Drug User Fee Amendments ("PDUFA"). PDUFA fees apply to both drugs and biologics. Sponsors may seek a waiver of these fees in certain limited circumstances, including a waiver of the application fee for the first BLA or NDA submitted by a small business and its affiliates. Investigational product candidates with an ODD are not subject to the BLA application fee unless the product application also includes a non-orphan indication.

The FDA reviews a BLA to determine, among other things, whether a biologic is safe, pure, and potent (i.e., effective) for its intended use and whether its manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Under PDUFA, the FDA has a goal date of ten months from the date a standard BLA is accepted for "filing" to review and act on the submission, and six months from the date of acceptance of a BLA that has received a Priority Review Designation. However, the time between submission and filing can add an additional two months as FDA conducts a preliminary review to ensure that the BLA is sufficiently complete to permit substantive review. Formal FDA review of the BLA does not begin until FDA has accepted it for filing. These are goal dates for FDA to take action on an application, and they are not guaranteed. The FDA may refer an application in some cases to an advisory committee for its independent review. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation to FDA as to whether the application should be approved and under what conditions. The FDA is not bound by advisory committee recommendations, but it considers them carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the locations where the investigational product candidate is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMPs and are adequate to assure consistent production of the product within required specifications. An important part of a BLA is a lot release protocol that the sponsor will use to test each lot of product made after BLA approval, as well as the FDA's own test plan that will be used for confirmatory testing of each post-approval product lot that is made before it is released to the public. If the FDA determines that the data and information in the application are not acceptable, then the FDA will outline the deficiencies and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA, it will either issue an approval letter or a Complete Response Letter ("CRL"). The approval letter authorizes commercial marketing of the biologic with approved prescribing information for specific approved indications. On the other hand, a CRL indicates that the review cycle of the application is complete, but the BLA cannot be approved in its present form. A CRL usually describes the specific deficiencies and the actions the sponsor must take to correct those deficiencies. A sponsor that receives a CRL must resubmit the BLA after addressing the deficiencies, withdraw the application, or request a hearing. Even if such additional data and information are submitted, the FDA may decide the resubmitted BLA still does not satisfy the approval criteria.

Following marketing approval, a sponsor may need to fulfill certain post-marketing requirements ("PMRs") or post-marketing commitments ("PMCs"). These may include Phase 4 studies that are used to gain additional experience from the treatment of patients for the intended therapeutic indication. The trials may be agreed upon prior to approval, or the FDA may require them if new safety issues emerge. A deferred pediatric study, if required (and not waived) under the Pediatric Research Equity Act ("PREA"), may also be conducted post-approval if the product includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration.

BLA approval may also include a risk evaluation and mitigation strategy ("REMS") that requires sponsor post-marketing regulatory efforts. A REMS is a safety strategy to manage a known or potential serious risk associated with a drug or biologic and to enable patients to have continued access to such medicines by managing their safe use. A REMS may include medication guides, physician communication plans, or elements to assure safe use ("ETASU") such as restricted distribution methods, patient registries, and other risk minimization tools.

FDA may withdraw the product approval if the sponsor does not comply with PMRs, PMCs, a REMS program, or other post-marketing requirements. The FDA may also request that a product be recalled for an identified safety issue. Finally, new legislative or regulatory requirements may be enacted or established, FDA policies may change, or FDA may not achieve its PDUFA goal dates, all of which could impact the timeline for development programs and regulatory approval.

FDA Expedited Review Programs for Serious Conditions

Under various statutory and regulatory authorities, the FDA has authority to review and approve certain investigational product candidates on an expedited basis if the investigational product candidates are intended to treat a serious condition and meet other requirements. These expedited programs are discussed below.

RMAT Designation. In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act. Regenerative medicine therapies to treat, modify, reverse, or cure serious conditions and that meet the appropriate criteria may be eligible for RMAT designation as well as FDA's other expedited programs (i.e., fast track, breakthrough therapy, priority review designations or accelerated approval). Regenerative medicine therapies receiving RMAT designation must meet the same standards for approval as any other biological product, including demonstrating the product's safety and effectiveness. As described in Section 3033 of the 21st Century Cures Act, an investigational product candidate is eligible for RMAT designation if:

- It is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products (except for those regulated solely under Section 361 of the PHS Act and 21 C.F.R. Part 1271);
- It is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and
- Preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

A request for an RMAT designation can be included in a new IND, or submitted as an amendment to an existing IND. As with other expedited programs, the FDA can withdraw an RMAT designation that has been granted if the designation criteria are no longer met. Benefits of the designation include, among others, early FDA interactions, and potential accelerated approval based on surrogate or intermediate endpoints. Additionally, the RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over available therapies. Receiving an RMAT designation is not the same as receiving FDA product approval. The FDA granted a RMAT designation to laromestrocel for the treatment of mild AD on July 5, 2024.

Fast Track Designation. The fast-track designation is intended to expedite or facilitate the process for reviewing new drug and biologic drug products that meet certain criteria. Specifically, investigational product candidates are eligible for this designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor may have the opportunity for more frequent interactions with FDA about the product development program. The FDA may review sections of the marketing applications on a rolling basis before the complete application is submitted if the sponsor provides a schedule for the submission of the application sections, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section. A fast-track designation may be rescinded if the investigational product candidate no longer meets the qualifying criteria for the designation. Receiving a fast-track designation is not the same as receiving FDA product approval. The FDA granted fast-track designations to laromestrocel for the treatment of HLHS on August 4, 2022 and for the treatment of mild AD on July 16, 2024.

Priority Review Designation. An investigational product candidate is eligible for priority review designation if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. The FDA will attempt to direct additional resources to the evaluation of an application for a priority review-designated investigational product candidate in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to the standard ten months for review, but this shortened review period is not guaranteed. Receiving a priority review designation is not the same as receiving FDA product approval.

Breakthrough Therapy Designation. A sponsor may seek FDA designation of an investigational product candidate as a "breakthrough therapy" if the investigational product candidate is intended, alone or in combination with one or more other products, to treat a serious condition and preliminary clinical evidence indicates that the investigational product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of a fast-track designation, as well as more intensive FDA interaction and guidance. If an investigational product candidate receives this designation, then the FDA will work to expedite the development and review of that investigational product candidate. A breakthrough therapy designation may be rescinded if the product no longer meets the qualifying criteria for the designation. Receiving a breakthrough therapy designation is not the same as receiving FDA product approval.

Accelerated Approval. An investigational product candidate intended to treat a serious condition may be eligible for accelerated approval upon a determination that the investigational product candidate provides a meaningful advantage over available therapies and 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require that a sponsor perform one or more post-approval studies to verify and describe the product's predicted effect on irreversible morbidity or mortality or other clinical benefit, and that the sponsor submit copies of all promotional materials in advance of their use. FDA has the legal authority to require that the sponsor begin the post-marketing clinical trials before accelerated approval is granted, or that the studies be underway within a particular timeframe after accelerated approval. If the confirmatory post-marketing clinical trials fail, then FDA can seek expedited withdrawal of the drug product from the market. All of these factors could adversely impact the timing of commercial launch and continued marketing of the product. Accelerated approval is an approval pathway, not a designation like the other examples listed above.

Even if an investigational product candidate qualifies for one or more of these programs, the standard for approval (i.e., safety and effectiveness) does not change. We may explore one or more of these opportunities for Longeveron's investigational product candidate as appropriate, as the programs are not mutually exclusive.

Marketing Exclusivity

In the case of biologic drugs, several types of marketing exclusivity may apply:

- Reference product exclusivity;
- Orphan drug exclusivity; and
- Pediatric exclusivity.

Reference Product Exclusivity

We believe that the FDA will regulate laromestrocel as a new biologic and will require submission and approval of a BLA under the PHS Act. The PHS Act includes a framework for determining when a biologic is a "reference product" and therefore eligible for marketing exclusivity. The reference product is the single biological product against which a biosimilar (a product that is highly similar to and has no clinically meaningful differences from the reference product) or an interchangeable biosimilar (a product that is both biosimilar to, and will produce the same clinical result as, the reference product) is evaluated.

The FDA must determine the date of "first licensure" (i.e., approval) of a biologic which will, in turn, determine whether that biologic qualifies as a reference product that will be eligible for statutory exclusivity (and when such exclusivity will expire). Typically (but not always) the date of approval is the date of first licensure. The FDA will not approve a biosimilar or interchangeable biosimilar until the date that is 12 years after the date on which the reference product was first approved. However, the FDA may receive an application for a biosimilar or interchangeable biosimilar four years after the date on which the reference product was first approved. These 12- and four-year terms are each extended by six months if the product has been awarded pediatric exclusivity.

Legal uncertainties remain about the FDA's application of the date of first licensure and statutory exclusivity provisions to cell therapy products. At the appropriate time, we intend to provide information to the FDA so that the FDA can determine the date of first licensure of laromestrocel (or any other investigational product candidate that will be regulated as a biologic) and the date from which statutory exclusivity will begin to run. However, the FDA may not make an immediate decision about the date of first licensure at the time it approves a new biologic. Furthermore, there is currently no precedent showing how the FDA will apply this statutory framework to a cell therapy product. The law in this area will likely continue to evolve.

Orphan Drug Designation and Exclusivity.

Congress enacted the Orphan Drug Act in 1983 to spur development of drugs and biologics to treat diseases or conditions affecting few U.S. patients. The FDA may grant an ODD for a drug or biologic drug being developed to treat a "rare disease or condition," defined as affecting fewer than 200,000 persons in the U.S. or affecting more than 200,000 persons in the U.S. but for which there is no reasonable expectation that development costs will be recovered from U.S. sales of the product. A request for ODD must be submitted to the FDA before a marketing application is submitted (i.e., BLA or NDA), but there is no assurance that FDA will award an ODD if requested. In the fourth quarter of 2021, the FDA granted ODD to Longeveron's laromestrocel for the treatment of HLHS.

An ODD does not change the regulatory review standards of safety and effectiveness and does not shorten the length of the FDA review or approval process. If an investigational product candidate with an ODD subsequently receives the first FDA approval for the disease or condition for which it has such designation, then the approved product may be eligible to receive orphan drug exclusivity ("ODE") that prevents the FDA from approving any other applications to market the same drug or biologic for the same rare disease or indication for seven years, except in several specific circumstances including, among others, demonstrating clinical superiority of a new product vs. the product with ODE because of greater safety, greater effectiveness, or making a major contribution to patient care. Even if an investigational product candidate has an ODD, there is no guarantee that the FDA will award ODE upon approval.

Competitors may receive approval of either a different product for the same use or indication, or the same product for a different use or indication. Approved drugs and biologics can also be used by physicians off-label, which is within the scope of their practice of medicine. Accordingly, ODE is not an absolute protection against potentially competing products. Moreover, an ODE awarded to another sponsor could block FDA approval of one of Longeveron's investigational product candidates for seven years.

The law involving ODDs and ODEs, including the FDA's interpretation of "same drug," is continuing to evolve. Most notably, the U.S. Court of Appeals for the Eleventh Circuit issued a decision in *Catalyst Pharmaceuticals, Inc. v. Becerra* in September 2021 that significantly modified the FDA's longstanding interpretation and application of the scope of ODE. In *Becerra*, the court held that ODE applied to all uses or indications within an orphan-designated disease, not only to the approved use or indication within the designated disease as stated in FDA regulations and as applied by the FDA in practice. Although the FDA announced in January 2023 that it would only apply the *Becerra* court's decision to the specific parties involved in that case, it is possible that the FDA could face additional administrative or legal challenges to its interpretation of the scope and applicability of ODD and ODE, as well as changes to the FFDCA itself.

In addition to the potential award of a seven-year ODE period upon product approval, the benefits of an ODD also include eligibility for certain research tax credits and a waiver of the marketing application fee otherwise required under PDUFA. An application for a prescription product with an ODD is not subject to an application fee unless the application also includes an indication for a non-rare disease or condition as well. Products with an ODD, and whose sponsors meet the financial criteria (i.e. having less than $50 million in gross worldwide revenue during the preceding year), are also exempt from program fees otherwise required under the PDUFA.

Pediatric Exclusivity. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity (e.g., ODE) if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Post-approval Requirements. Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and

advertising and promotion of the product. There also are continuing, annual program fees under PDUFA for any marketed products. Establishment registration of drug and biologic drug manufacturers and their subcontractors with FDA and certain state agencies subjects those entities to periodic unannounced inspections by the FDA for compliance with cGMPs, imposing certain procedural and documentation requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort for production and quality control to maintain compliance with cGMPs and other regulatory requirements.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials 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 untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of approved products. A company can make only those claims that were approved by the FDA in the application for marketing approval and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for certain patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of approved treatments, as the practice of medicine is outside the scope of FDA's authority. However, the FDA restricts manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal penalties against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory authorities have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

U.S. Federal and State Fraud and Abuse Laws

Although our investigational product candidates are not currently reimbursed by government healthcare programs such as Medicare or Medicaid, any future reimbursement from federal and/or state healthcare programs could expose our business to broadly applicable fraud and abuse laws and other healthcare laws and regulations that would regulate the business.

Federal Stark Law

If in the future some of our revenues are derived from federal healthcare programs, we may be subject to the federal self-referral prohibitions, commonly known as the Stark Law. Where applicable, this law prohibits a physician from referring Medicare patients to an entity providing "designated health services" such as laboratory and other diagnostic services and prescription drugs that are furnished at an entity if the physician or a member of such physician's immediate family has a "financial relationship" with the entity, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, civil monetary penalties of up to $15,000 per claim submitted, adjusted for inflation, and three times the value of each such service and exclusion from the federal healthcare programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the federal False Claims Act ("FCA"). The statute also provides for a penalty of up to $100,000, adjusted for inflation, for a circumvention scheme. The Stark Law is a strict liability statute, which means proof of specific intent to violate the law is not required. In addition, the government and some courts have taken the position that claims presented in violation of the various statutes, including the Stark Law, can be considered a violation of the FCA (described below) based on the contention that a provider impliedly certifies compliance with all applicable laws, regulations and other rules when submitting claims for reimbursement.

Federal Anti-Kickback Statute

We will also be subject to the federal Anti-Kickback Statute if any of our investigational product candidates or services become reimbursable by government healthcare programs. The Anti-Kickback Statute is broadly worded and prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person covered by Medicare, Medicaid or other governmental programs, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs or (iii) the purchasing, leasing or ordering or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other governmental programs. Certain federal courts have held that the Anti-Kickback Statute can be violated if "one purpose" of a payment is to induce referrals. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation, making it easier for the government to prove that a defendant had the requisite state of mind or "scienter" required for a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA, as discussed below. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the FCA. Violations of the federal Anti-Kickback Statute can also result in criminal penalties, including criminal fines of more than $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. In addition to a few statutory exceptions, the Office of Inspector General ("OIG") has published safe-harbor regulations that outline categories of activities that are deemed protected from prosecution under the Anti-Kickback Statute provided all applicable criteria are met. The failure of a financial relationship to meet all of the applicable safe harbor criteria does not necessarily mean that the particular arrangement violates the Anti-Kickback Statute. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

False Claims Act

Both federal and state government agencies have continued civil and criminal enforcement efforts as part of numerous ongoing investigations of healthcare companies and their executives and managers. Although there are a number of civil and criminal statutes that can be applied to healthcare providers, a significant number of these investigations involve the FCA. These investigations can be initiated not only by the government but also by a

private party asserting direct knowledge of fraud. These "qui tam" whistleblower lawsuits may be initiated against any person or entity alleging such person or entity has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government or has made a false statement or used a false record to get a claim approved. In addition, the improper retention of an overpayment for 60 days or more is also a basis for an FCA action, even if the claim was originally submitted appropriately. Penalties for FCA violations include fines ranging from $14,308 to $28,619 for each false claim, adjusted for inflation, plus up to three times the amount of damages sustained by the federal government. An FCA violation may provide the basis for exclusion from the federally funded healthcare programs.

State Fraud and Abuse Laws

Several states have also adopted or may adopt similar self-referral, anti-kickback, fraud, whistleblower and false claims laws as described above. The scope of these laws and the interpretations of them vary by jurisdiction and are enforced by local courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by Medicaid programs and any third-party payer, including commercial insurers or to any payer, including to funds paid out of pocket by a patient. A determination of liability under such state fraud and abuse laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Other Healthcare Laws

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") established several separate criminal penalties for making false or fraudulent claims to insurance companies and other non-governmental payers of healthcare services. These two additional federal crimes are: "Healthcare Fraud" and "False Statements Relating to Healthcare Matters." The Healthcare Fraud statute prohibits knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from government sponsored programs. The False Statements Relating to Healthcare Matters statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact by any trick, scheme or device or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines or imprisonment. This statute could be used by the government to assert criminal liability if a healthcare provider knowingly fails to refund an overpayment. These provisions are intended to punish some of the same conduct in the submission of claims to private payers as the federal FCA covers in connection with governmental health programs. In addition, the Civil Monetary Penalties Law imposes civil administrative sanctions for, among other violations, inappropriate billing of services to federally funded healthcare programs and employing or contracting with individuals or entities who are excluded from participation in federally funded healthcare programs. Moreover, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration, including waivers of copayments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to $20,000 for each wrongful act. Furthermore, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and civil FCA, which can impose additional penalties associated with the wrongful act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts, and statutory or common law fraud.

Pharmaceutical and medical device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, the U.S. federal Anti-Kickback Statute, FCA, Consumer Fraud Act, fee splitting, patient brokering and other federal laws and regulations, as well as similar foreign laws in jurisdictions outside the U.S., where applicable, involving fraud and abuse, price reporting, data privacy and security, and transparency. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical

industry, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; requirements to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; requirements relating to pricing and marketing information; requirements to track and report gifts and other remuneration and items of value provided to physicians, marketing personnel and entities other healthcare providers and entities or that require the registration of pharmaceutical sales representatives; requirements regarding the registration of pharmaceutical sales representatives; and other applicable laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Violation of any of such applicable laws or regulations may result in penalties, including, either separate or in combination and without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which the product will be covered and reimbursed by government payors (e.g., federal and state healthcare programs), third-party payors (e.g., commercial insurance and managed healthcare organizations), and other payors (e.g., foreign government healthcare programs). Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. For example, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by payors, that an adequate level of reimbursement will be established even if coverage is available or that the payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Decisions regarding the extent of coverage and amount of reimbursement to be provided are generally made on a plan-by-plan basis, meaning one third-party payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product, and require providers to show medical necessity for use, to each payor separately. This process can be time-consuming, with no assurance that coverage and adequate reimbursement will be applied consistently or even obtained.

Similar challenges to obtaining coverage and reimbursement for pharmaceutical or biologic products will apply to companion diagnostics. For example, for products administered under the supervision of a physician, the difficulty in obtaining coverage and adequate reimbursement may be increased because of the higher prices often associated with such drugs. Additionally, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement of the companion pharmaceutical or biologic product. However, separate reimbursement for the product itself, the companion product, or the treatment or procedure for which the product is used may not be available, which, in turn, may also impact utilization.

Payors are also increasingly reducing reimbursements for pharmaceutical products and services through continued implementation of cost-containment programs, including price controls and value-based care initiatives, requirements for substitution of generic products and restrictions on coverage and reimbursement, which could further limit sales of any product. In addition, payors continue to question safety and efficacy while also challenging the prices charged, examining medical necessity, and reviewing the cost effectiveness of pharmaceutical products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases of this nature surrounding reimbursement for any product or a decision by a government and third-party payor not to cover a product could result in reduced physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or

indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability of manufacturers to sell products profitably.

Healthcare Reform

In the U.S. and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("ACA") was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the U.S. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on each covered entity engaged in the business of manufacturing or importing branded prescription drugs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected (often referred to as "5i drugs"); expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges that would either repeal, or repeal and replace, all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated, effective January 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 Consolidated Appropriations Act permanently eliminated, effective January 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 2021, also eliminated the health insurer tax. Other legislative changes have also been adopted since the ACA was enacted, including mandatory sequestration (e.g., aggregate reductions of certain Medicare payments of up to 2%), which will remain in effect through fiscal year 2031 absent Congressional action.

We expect such judicial and Congressional challenges to continue. There has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to reform government program reimbursement methodologies for pharmaceutical products and bring more transparency to product pricing and the relationship between pricing and manufacturer patient programs.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, which amends the FFDCA, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

On July 9, 2021, former President Biden signed the "Executive Order on Promoting Competition in the American Economy," which focused on increasing competition in several industries, including the pharmaceutical and biotechnology industries. Among other things, the Executive Order directed the Department of Health and Human Services to increase support for generic and biosimilar drugs, continue to improve the approval framework for generics and biosimilars, to issue a comprehensive plan to combat high prescription drug prices and price gouging, identify efforts to impeded generic and biosimilar competition, and to standardize plan options in the National

Health Insurance Marketplace to improve competition and consumer choice. The Executive Order also encouraged the FTC to ban unfair anticompetitive conduct or agreements such as "pay for delay" and similar agreements, in which brand-name drug manufacturers pay generic drug manufacturers to stay out of the market, resulting in an estimated $3.5 billion increase in drug prices per year.

The second Trump administration's approach to healthcare reform efforts and legislative changes continues to evolve. On July 4, 2025, President Trump signed into law a federal budget reconciliation act, Public Law 119-21, commonly known as the One Big Beautiful Bill Act (the "OBBBA"). The OBBBA includes major reductions in federal healthcare spending and is projected to be among the largest reductions of federal funding in history. These reductions include projected reductions in federal spending for Medicaid and certain Medicare benefits, as well as changes to eligibility and redetermination requirements that are expected to reduce the number of Medicaid beneficiaries and Medicaid waiver beneficiaries. States are required to implement new Medicaid eligibility and redetermination requirements by December 31, 2026, although the Secretary of Health and Human Services may grant a one-time extension for states demonstrating good-faith implementation efforts, but in no event later than December 31, 2028. The OBBBA is expected to accelerate the projected depletion of Medicare's Hospital Insurance Trust Fund, which contributes to payment for hospital services, and makes changes in the established Affordable Care Act marketplace.

The OBBBA significantly increases the regulatory requirements to obtain and maintain beneficiary eligibility in Medicaid. Accordingly, the number of individuals covered by Medicaid is expected to decrease, and coverage for certain individuals may remain uncertain, including individuals who are dually eligible for Medicare and Medicaid. Further changes to the Affordable Care Act could adversely affect the insurance market for certain populations.

Further, the OBBBA includes several changes that are relevant to the prescription drug marketplace. The OBBBA requires pharmacy benefit managers to maintain transparency in cost and pricing data in certain Medicaid managed care plans. However, the OBBBA modifies the drug price negotiation protections enacted in 2022 under the Inflation Reduction Act for Medicare by expanding the list of drugs exempt from negotiation and delaying the implementation of additional price controls for some products. It is unclear what the magnitude of this impact will be on cost-sharing capacity and overall consumer behavior.

Human Capital Management

As of December 31, 2025, we had 37 full-time employees plus 1 employee on leave of absence, zero part-time employees and zero full-time consultants. Among those employees, 2 are M.D.s and 2 have Ph.D. degrees, 2 are Certified Public Accountants, and 1 has a J.D. degree. Of these full-time employees, 26 are engaged in research and development activities. The Company is currently undertaking certain cost-savings efforts, including the furlough of certain Company employees, which became effective on or about February 16, 2026.

None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

The Company sets annual Corporate Goals and Objectives that are communicated to all employees.

See Part III of this Form 10-K for information about our Executive Officers, non-employee Directors and other key employees.

Available Information

The Company was formed as a Delaware limited liability company in October 2014 and converted into a Delaware corporation in February 2021 in connection with our initial public offering ("IPO"). Our principal executive offices are located at 1951 NW 7th Avenue, Suite 520 Miami, Florida 33136 and our telephone number is (305) 909-0840.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are filed with the Securities and Exchange Commission ("SEC"). We are subject to the informational requirements of the Exchange Act, and we file or furnish reports, proxy statements and other information with the SEC. Such reports and other information we file with the SEC are available free of charge at our website *www.longeveron.com* when such reports are available on the SEC's website. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at *www.sec.gov*.

Longeveron periodically provides other information for investors on our corporate website, including press releases and other information about financial performance, information on corporate governance and presentations. Our website address is *www.longeveron.com*, and we make our filings with the SEC available on the Investor Relations page of our website. Our references to website URLs are intended to be inactive textual references only. The information found on, or that can be accessed from or that is hyperlinked to, our website does not constitute part of, and is not incorporated into, this Form 10-K. Our Class A common stock is traded on the Nasdaq Capital Market under the symbol "LGVN".

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations and financial results. Please refer to Item 1A "Risk Factors" of this 10-K below for additional discussion of the risks summarized in this Risk Factors Summary.

Risks Relating to our Business

- We have ongoing challenges with respect to our liquidity and access to capital;
- We have a history of losses and may not be able to achieve profitability going forward, and may not be able to raise additional capital necessary to continue as a going concern;
- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability; and
- There are no FDA-approved allogeneic, cell-based therapies for Aging-related Frailty, Alzheimer's disease (AD), or other aging-related conditions, nor HLHS, pediatric DCM or other cardiac-related indications. This could complicate and delay FDA approval of our investigational product candidate for these indications, or other indications we study or will study.

Risks Related to Intellectual Property

- If our trade secret and patent position does not adequately protect our investigational product candidates and their uses, others could compete against us more directly, which could harm our business and have a material adverse effect on our business, financial condition, and results of operations;
- If certain license agreements are terminated, our ability to continue clinical trials and commercially market products could be adversely affected;
- If all of the Company's intellectual property has not been properly assigned to the Company, our business, financial condition, results of operation, and prospects could be adversely affected; and
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Risks Related to Regulatory Approval and Other Government Regulations

- We are substantially dependent on the successful development, regulatory approval and commercialization of laromestrocel, and we cannot assure you that we will obtain regulatory approval or successfully commercialize this investigational therapy;
- If we are not able to successfully develop and commercialize our investigational product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations;
- Our CMC readiness and ability to manufacture laromestrocel for commercialization and any future product candidates for clinical or commercialization may require significant additional investment, be delayed or be unsuccessful; and
- Even if we complete clinical development, regulatory approval may be delayed, limited, or subject to burdensome conditions, which could materially affect our commercial prospects.

Risks Related to Our Dependence on Third Parties

- We currently depend upon third parties for services and raw materials needed for the manufacture of our investigational product candidates, and if these products are successfully commercialized, we may become dependent upon third parties for product distribution. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver could be compromised;
- Use of third-party manufacturers may increase the risk that we will not have adequate quantities of our investigational product candidates;
- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential investigational product candidates; and
- Because we have, at present, made a strategic decision to use third-party manufacturers in the future, they will likely be dependent upon their own third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

Risks Related to the Discovery, Development and Commercialization of Our Investigational Product Candidates

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

Risks Related to Our Class A Common Stock and the Securities Market

- We will need to raise substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, scale back or discontinue some of our investigational product candidate development programs or commercialization efforts;
- If we continue to fail to meet the requirements for continued listing on Nasdaq, our Class A common stock could be delisted from trading on Nasdaq, which would likely reduce the liquidity of our Class A common stock and could cause our trading price to decline; and
- Provisions in our certificate of incorporation, as amended (the "Certificate of Incorporation") and bylaws (the "Bylaws") and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A common stock.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

- We have never commercialized an investigational product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. In addition to the other information in this 10-K, the following risk factors should be considered carefully in evaluating us. You should consider and read carefully all of the risks and uncertainties described below and the other information in this report, including our financial statements and related notes appearing elsewhere in this 10-K and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision with respect to our securities. The occurrence of any of the following risks, or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations or cash flows. In any such case, the market price of our Class A common stock could decline and you could lose all or part of your investment. This 10-K also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including the risks and uncertainties described below. For a summary of these risk factors, please see "Risk Factors Summary" beginning on page 26 of this 10-K.

Risks Related to our Business

We have a history of losses and may not be able to achieve profitability going forward, and may not be able to raise additional capital necessary to continue as a going concern.

We have experienced significant losses since inception and, at December 31, 2025 and 2024, had an accumulated deficit of approximately $132.3 million and $109.6 million, respectively. We expect to incur additional losses in the future and expect the cumulative losses to increase. We expect our operating expenses to increase and it is not likely that our grant revenues will fully fund our clinical programs.

As of December 31, 2025, we had cash and cash equivalents of $4.7 million. As a result of the recently completed private placement financing referenced in Note 14, Subsequent Events, and based on current operating plans, the Company expects that its cash and cash equivalents as of December 31, 2025 plus the $15.9 million in gross proceeds from the private placement will fund operations into the fourth quarter of 2026.

To continue as a going concern, we will need to obtain additional capital, which we will likely obtain through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. There are no assurances that we would be able to raise additional capital or on terms favorable to us. Our recurring losses from operations and negative cash flow raise substantial doubt about our ability to continue as a going concern without sufficient capital resources and we have included an explanatory paragraph in the notes to our financial statements for the year ended December 31, 2025, with respect to this uncertainty. Further, the report of our independent registered public accounting firm with respect to our audited financial statements for the year ended December 31, 2025 included an emphasis of matter paragraph stating that our recurring losses from operations and continued cash outflows from operating activities raised substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this going concern uncertainty and have been prepared under the assumption that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

If we are unable to continue as a going concern, we may be forced to liquidate our assets, which would have an adverse impact on our business and developmental activities. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The reaction of investors to the inclusion of a going concern statement by our independent registered public accounting firm and our potential inability to continue as a going concern may materially adversely affect our stock price and our ability to raise new capital. Our ability to continue as a going concern is dependent on our available cash, how well we manage that cash, and our operating requirements. If we are unable to raise additional capital when needed, we would be forced to delay, reduce or eliminate our clinical trial programs, commercialization efforts and other business activities.

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any material revenue from product sales. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, building and equipping our research and development laboratories, building and equipping our manufacturing suites, raising capital, acquiring raw materials for manufacturing, investigational product candidate development and manufacturing, securing related intellectual property rights and conducting clinical trials of our laromestrocel cellular therapy investigational product candidate. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage biotechnology companies in rapidly evolving fields, including but not limited to changes in FDA or foreign body regulatory oversight of products. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities.

Such a transition may involve substantial additional capital requirements in order to launch and market a product, changes in the use of proceeds, and significant adjustment to personnel, compared to a clinical-stage development company. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have ongoing challenges with respect to our liquidity and access to capital.

As we advance the preclinical and clinical development of our programs, we expect to continue to incur significant expenses and operating losses, for which we do not have offsetting revenue. We expect that our sales, research and development and general and administrative costs will increase in connection with conducting additional preclinical studies and clinical trials for our current and future programs and product candidates, contracting with contract research organizations ("CROs") to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

As of December 31, 2025, we had $4.7 million in cash and cash equivalents. To date, we have financed our operations primarily through public and private equity financings, grant awards, and fees generated from clinical trial revenue and contract manufacturing services. There are no assurances that we will be able to continue to finance operations through these means, and our inability to generate sufficient revenue in the near term may have an adverse impact on our business, operations and prospects.

If the potential of our investigational product candidates to treat diseases is not realized, the value of our technology and our development programs could be significantly reduced.

Our team is currently exploring the potential of our investigational product candidates to treat diseases. We have not yet proven in clinical trials that our investigational product candidates will be a safe and effective treatment for any disease or condition. Our investigational product candidates are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their marketing approval or commercial use. We have not yet completed all of the testing necessary to allow us to make a determination that serious unintended consequences will not occur. If the potential of our investigational product candidates to treat disease is not realized, the value of our technology and our development programs could be significantly reduced. Because our investigational product candidates are based on MSCs, any negative developments regarding the therapeutic potential or side effects of our MSCs, or regarding scientific and medical knowledge about MSCs in general, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of investigational product candidates based on new technologies. The novel nature of our investigational product candidates creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third-party reimbursement, and market acceptance. For example, although the FDA has approved several cell therapy products, the FDA has relatively limited experience with regulating these kinds of therapies, and its regulations and policies are still evolving. As a result, the pathway to regulatory approval for our investigational product candidates may be more complex and lengthier.

Additionally, stem cells that are taken from one person and transplanted into a different individual may pose additional risks. For example, stem cells that are allogeneic (i.e., taken from one individual and given to a different person) and not autologous (i.e., taken from, and given to, the same individual) are subject to donor-to-donor variability, which can make standardization more difficult. As a result of these factors, the development and commercialization pathway for our therapies may be more complex and lengthier, and subject to increased uncertainty, as compared to the pathway for new conventional (i.e., new chemical entity) drugs.

There are no FDA-approved allogeneic, cell-based therapies for Aging-related Frailty, Alzheimer's disease (AD), or other aging-related conditions, nor HLHS, pediatric DCM or other cardiac-related indications. This could complicate and delay FDA approval of our investigational product candidate for these indications, or other indications we study or will study.

Although the FDA has approved several cell therapy products, there are no allogeneic cell-based or stem cell therapies currently approved by the FDA for the treatment of Aging-related Frailty or the other indications we are studying. There are also no conventional drugs or therapies currently approved by the FDA with stated indications for Aging-related Frailty, Aging, or Frailty.

According to the FDA, "Aging-related Frailty" does not have a definition that is acceptable for characterizing the conditions for regulatory purposes, and there are no precedents for regulatory approvals of this indication. This could prevent, complicate and/or delay regulatory approval of our investigational product candidate for these indications to the extent that the Company may continue to pursue this indication.

The FDA and the Japanese PMDA have both indicated that the concept of "Frailty" as an indication will require additional clinical data and discussion before future pivotal trials and marketing authorization. Because the condition of Frailty lacks consensus, there is no guarantee that PMDA, FDA or any regulatory agency will agree to an approvable indication, that these regulatory authorities will reach a consensus regarding the definition of the condition, or that they will agree on clinical endpoints that would be considered acceptable for demonstrating clinically meaningful benefit. More specifically, our ability to begin Phase 3 (i.e., pivotal) trials in a "Frailty" or "Aging-related Frailty" indication would depend on our subsequent interactions with FDA where we would discuss the size and scope of the next program, the appropriate target patient population (i.e., defining the indication), and agreement on one or more primary endpoints that demonstrate clinically meaningful outcome.

It is possible that the FDA may never recognize "aging" as a disease and may never agree to a definition of "Aging-related Frailty" primarily due to a lack of consensus on the definitions amongst clinicians, researchers and regulators, an insufficient understanding of the underlying pathophysiologic mechanisms that cause any or all of the manifestations, or both. To obtain FDA approval for any indication for the disease states we are studying, we will have to demonstrate, among other things, that our investigational product candidates are safe and effective for that indication in the target population. The results of our clinical trials must be statistically significant, meaning that there must be sufficient data to indicate that it is unlikely the outcome occurred by chance. The FDA will also require us to demonstrate an appropriate dose (i.e., number of cells) and dosing interval for our investigational product candidates, and to identify and define treatment responders, which may require additional clinical trials. As a result, the clinical endpoints, the criteria to measure the intended results of treatment, and the correct dosing for our cell-based therapeutic approaches for "Aging-related Frailty" may be difficult to determine. To the extent we decide to pursue this indication, these challenges may prevent us from developing and commercializing products on a timely or profitable basis, or at all.

If we are not able to recruit and retain qualified management and scientific personnel, we may fail in developing our technologies and investigational product candidates.

Our future success depends to a significant extent on the skills, experience, and efforts of the principal members of our scientific and management personnel. These members include Joshua M. Hare, M.D. and our staff of scientific consultants. Our co-founder, Dr. Hare, remains employed by UM, and provides services to us as a consultant on a limited basis. The loss of Dr. Hare or any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Competition for regulatory, clinical manufacturing and management personnel in the pharmaceutical industry is intense. We may be unable to recruit or retain personnel with sufficient management skills in the area of cell therapeutics or attract or integrate other qualified management and scientific personnel in the future.

Our investigational product candidates represent new classes of therapy that the marketplace may not understand or accept.

Even if we successfully develop and obtain regulatory approval for our investigational product candidates, the market may not understand or accept them. We are developing investigational product candidates that represent novel treatment approaches and will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The degree of market acceptance of any of our future developed and potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of our investigational product candidates or future approved products and their perceived advantage over alternative treatment methods;
- our ability to demonstrate that our cell-based investigational product candidates have a clinically significant effect, initially for Aging-related Frailty, AD, HLHS, and other disease states for which we may seek marketing approval;
- ethical controversies that may arise regarding the use of stem cells or human tissue of any kind, including adult stem cells, adult bone marrow, and other adult tissues derived from donors;
- adverse events involving our investigational product candidates or candidates of others that are cell based;
- once approved, our ability to supply a sufficient amount of our products to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and
- once approved, the cost of our products and the reimbursement policies of government and third-party payors.

If the healthcare community does not accept our investigational product candidates or future approved products for any of the foregoing reasons, or for any other reason, it could affect our sales or have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our dependence upon a limited supply of bone marrow donors and biologic growth media may impact our ability to produce sufficient quantities of our investigational product candidates as needed to complete our clinical trials, and if our trials are successful and our investigational product candidates are approved, to meet product demand.

The population of acceptable bone marrow donors is limited to volunteers between the ages of 18 and 45. In addition, potential donors are prescreened for a variety of health conditions and are only allowed to donate bone marrow a total of six times in their lifetime, further limiting the total number of potential donors. The amount of bone marrow donated may be insufficient for us to mass produce our investigational product candidates at a scale sufficient to meet our clinical trial needs or to produce a product, if approved, to meet future commercial demand at an acceptable cost. In addition, the expansion of MSCs through our proprietary manufacturing methods utilizes biologic growth media that may be in limited supply. Our investigational product candidates will be inherently more difficult to manufacture at commercial-scale than conventional pharmaceuticals, which are manufactured using precise chemical formulations and operational methods. Cost-effective production at clinical trial or commercial scale quantities may not be achievable.

Future government regulation or health concerns may also reduce the number of donors or otherwise limit the amount of bone marrow available to us. If we cannot secure quantities of bone marrow or biologic growth media sufficient to meet the manufacturing demands for our clinical trials, we might not be able to complete our clinical trials and obtain marketing approval for our investigational product candidates. Moreover, even if our clinical trials are successful and we obtain marketing approval for our investigational product candidates, our inability to secure enough bone marrow or biologic growth media to meet commercial product demand could limit our potential revenues.

Mesenchymal stem cells are biological entities derived from human bone marrow and therefore have the potential for disease transmission and can pose risks to the recipient.

MSC therapies require many manufacturing steps. Cells must be harvested from donor tissue, isolated, and expanded in cell culture to produce a sufficient number of cells for use. Each step carries risks for contamination by other cells, microbes, or adventitious agents. The transfer of cells into a recipient can also carry risks and complications associated with the procedure itself, and a recipient may reject the transplanted cells.

Further, the utilization of donated bone marrow creates the potential for transmission of cancer and communicable disease, including but not limited to human immunodeficiency virus ("HIV"), viral hepatitis, syphilis, Creutzfeldt-Jakob disease, and other viral, fungal, or bacterial pathogens. Although we and our suppliers are required to comply with federal and state regulations intended to prevent communicable disease transmission, we or our suppliers may fail to comply with such regulations. Further, even with compliance, our future products might nevertheless be viewed by the public as being associated with transmission of disease, and a clinical trial subject or patient who contracts an infectious disease might assert that the use of our investigational product candidate or future products resulted in disease transmission, even if the individual became infected through another source.

Any actual or alleged transmission of communicable disease could result in clinical trial subject or patient claims, litigation, distraction of management's attention, increased expenses, and adverse regulatory authority action. Further, any failure in screening, whether by us or other manufacturers of similar products, could adversely affect our reputation, the support we receive from the medical community, and overall demand for our future products. As a result, such actions or claims, whether or not directed at us, could have a material adverse effect on our reputation with our customers and our ability to market our future products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If our processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business and prospects could be negatively affected.

Our processing and storage facility is located in a region which experiences severe weather, notably hurricanes, from time to time. If this facility in Miami, Florida or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some, or all of the stored units of our investigational product candidates and it could force us to halt our clinical trial processes. The risk of tropical storm and hurricane activity historically rises on or about June 1st each year and subsides on or about November 30th each year. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major hurricane or tornado, flood, fire, earthquake, power loss, terrorist activity or other disasters and do not currently have a recovery plan for such disasters. If we underestimate our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Ethical and other concerns surrounding the use of stem cell therapy or human tissue may negatively affect public perception of us or our future products or investigational product candidates, or may negatively affect regulatory approval of our future products or investigational product candidates, thereby reducing demand for our future products.

The commercial success of our investigational product candidates will depend in part on general public acceptance of the use of MSC therapy for the prevention or treatment of human diseases. Although we do not use embryonic stem cells or fetal tissue, the public may not be able to, or may fail to, differentiate our use of adult MSCs from the use of embryonic stem cells or fetal tissue by others, which could result in a negative perception of our company or our future products or investigational product candidates, thereby reducing demand, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may obtain MSCs from volunteer adult bone marrow donors from non-profit organizations that collect and process tissue donations. Bone marrow donors receive payment, but ethical concerns have been raised by some about the use of donated human tissue in a for-profit setting, as we are doing. Future adverse events in the field of stem

cell therapy, changes in public policy, or changes to the FDA's regulatory approval framework for these products could also result in greater governmental regulation of our investigational product candidates or future products, and potential regulatory delays relating to their testing or approval.

We may eventually compete for product sales with other companies, many of which will have greater resources or capabilities than we have, or may succeed in developing better products or in developing products more quickly than we do, and we may not compete successfully with them.

We compete or may eventually compete with other companies and organizations that are marketing or developing therapies for our targeted disease indications, based on traditional pharmaceutical, medical device, or other non-cellular therapy and technologies. In addition, we have other potential competitors developing a variety of therapeutics, and in some cases, such as with AD, there may be tens or hundreds of companies seeking to commercialize therapeutics.

We also face competition in the cell therapy field from academic institutions and governmental agencies. Many of our current and potential competitors have greater financial and human resources than we have, including more experience in research and development and more established sales, marketing, and distribution capabilities.

We anticipate that competition in our industry will increase. In addition, the healthcare industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render investigational product candidates under development by us now or in the future, or any future products manufactured or marketed by us, non-competitive or otherwise obsolete.

Sales of our future products may involve a lengthy sales cycle.

Many factors are expected to influence the sales cycle for future products once they are approved. These factors include the future state of the market, the perceived value of our investigational product candidate(s), the evolution of competing technologies, insurance coverage or prior authorization requirements and changes in medical practices. Any of these may adversely affect our sales cycles and the rate of market acceptance of our future approved products.

We face risks related to health epidemics, pandemics, and outbreaks.

Global outbreaks of epidemics, pandemics, and other public health risks, such as COVID-19, historically have and may in the future continue to impact countries, communities, supply chains and markets. For example, the COVID-19 pandemic historically impacted our Bahamas Registry Trial business. It is also possible that public health risks could adversely affect our business, results of operations, financial condition or liquidity in the future. For example, they could impact the timing and enrollment of our collaborators' planned or ongoing clinical trials, delaying clinical site initiation, regulatory review and the potential receipt of regulatory approvals, payment of milestones under our license agreements and commercialization of one or more of our investigational product candidates, if approved. Epidemics, pandemics, and other public health risks could also disrupt the production capabilities of our contract manufacturing facility. Further, the continued mutation of viruses, including COVID-19 and other epidemics or pandemics may lead to ongoing illness in our workforce or contracting partners, which may leave individuals unable to work for periods of time. The impact of such epidemics, pandemics, and other public health risks are generally fluid and evolve over time, and therefore, we cannot currently predict the extent to which our business, clinical trials, results of operations, financial condition or liquidity would ultimately be impacted. In addition, epidemics, pandemics, and other public health risks could materially and adversely impact our operations due to, among other factors:

- a general decline in business activity;
- difficulty accessing the capital and credit markets on favorable terms, or at all, and a severe disruption and instability in the global financial markets, or deteriorations in credit and financing conditions which could affect our access to capital necessary to fund business operations;
- the potential negative impact on the health of our employees, especially if a significant number of them or any of their family members are impacted or if any of our senior leaders are impacted for an extended period of time;

- the potential negative impact on our ability to monitor the investigative sites participating in our clinical studies in person or even remotely, which could result in a deviation from pre-pandemic protocols and/or site monitoring and data management plans, and delays in our ability to perform data-related tasks dependent on communications with personnel at the investigative sites, such as resolution of open data queries, the cumulative effects of which could lead to delayed or missed identification of non-compliance with cGCPs, and/or unrecognized data errors;
- potential delays in the preparation and submission of applications for regulatory approval of our investigational product candidates, as well as potential delays in FDA's or another regulatory authority's ability to review applications in a timely manner consistent with past practices;
- potential difficulty in adequately overseeing and/or evaluating the manufacturing process at the facilities that will manufacture future commercial products; and
- a deterioration in our ability to ensure business continuity during a disruption.

Adverse global conditions, including macroeconomic uncertainty, may negatively impact our financial results.

Global conditions, dislocations in the financial markets, or continuing inflation could adversely impact our business. In addition, the global macroeconomic environment has been and may continue to be negatively affected by, among other things, instability in global economic markets, evolving U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the Russo-Ukrainian War, the Israeli-Palestinian conflict, the withdrawal of the United Kingdom from the European Union, United States military activity in Venezuela and the Caribbean, other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets, which may adversely affect our business.

We have been funded in part by government and non-profit association grant awards, which is not a guaranteed source of future funding.

The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, and changes in national health and welfare priorities, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our continued receipt of government and non-profit association funding is also dependent on the ability to adhere to the terms and provisions of the original grant and contract documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for the grants and contracts we have been awarded. The loss of government funds or non-profit association grant awards could have a material adverse effect on our clinical programs and on our business, financial condition, and results of operations. For additional detail regarding the grant awards, we have received from governmental and non-profit associations, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Grant Awards"* on page 88 of this report.

The use of our investigational product candidates or future products in individuals may expose us to product liability claims, and we may not be able to obtain adequate product liability insurance coverage.

Because of the nature of our investigational product candidates and future products, we face an inherent risk of product liability claims. None of our investigational product candidates have been widely used over an extended period of time, and therefore our safety data are limited. We derive the raw materials for our investigational product candidates from human donor sources, the manufacturing process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. We will need to increase our insurance coverage if and when we receive approval for and begin commercializing our investigational product candidates. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all. If we are unable to obtain insurance, or if claims against us substantially exceed our coverage, then our business could be adversely impacted. Whether

or not we are ultimately successful in any product liability litigation, such litigation either before or after product approval and marketing could consume substantial amounts of our financial and managerial resources and could result in, among other things:

- significant awards against us;
- substantial litigation costs;
- recall of future products or termination of clinical trials for our investigational product candidates;
- FDA withdrawal of marketing approval of future products or suspension or revocation of an IND for an investigational product candidate;
- injury to our reputation;
- withdrawal of clinical trial participants;
- withdrawal of clinical trial sites or investigators; or
- adverse regulatory action.

Any of these results could have a material adverse effect on our business, financial condition, and results of operations.

We face risks with respect to our contract development and manufacturing business.

We occasionally provide contract development and manufacturing services to third-parties and may, in the future, provide similar services to a limited number of customers that are developing their own cellular therapy treatments. We have experienced and may in the future experience diminished demand or loss of customers within our contract development and manufacturing services operations, which has in prior periods and may in the future have a significant impact on the income generated from this division of our business. Revenues from these services are not currently material to our financial results or operations. However, to the extent we engage in these activities, similar regulatory, ethical, supply chain, and demand risks apply whether we are developing and manufacturing our investigational product candidates of future products or investigational product candidates for our customers. Assisting customers in developing a product or investigational product candidate may result in incurring costs and expenses that are not reimbursable by the customer, including, if we are required to obtain regulatory approval that is specific to manufacturing a customer's product or product candidate. We must maintain stringent quality control measures, as failure to do so could lead to manufacturing defective products. Failure to manufacture regulatory compliant products or investigational product candidates could result in recalls, legal liabilities, and impact our relationship with current and future customers.

Risks Related to Intellectual Property

If our trade secret and patent position does not adequately protect our investigational product candidates and their uses, others could compete against us more directly, which could harm our business and have a material adverse effect on our business, financial condition and results of operations.

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our investigational product candidates. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions, and continues to be the subject of much litigation. Our trade secrets attempt to bridge the gap that threatens patent exclusivity for the protection of products derived from MSCs. Our trade secrets also are intended to remain valid and enforceable without regard to limitations such as term restrictions that are imposed on patents. Our trade secrets and know-how are the subject of various license agreements and confidentiality agreements as further discussed below.

The claims of existing U.S. and foreign patent applications and patents, and those patents that may issue in the future, or those to be licensed to us, that are owned by the Company or under an obligation of assignment to the Company, may not confer on us significant commercial protection against competing products, methods, or processes.

Furthermore, to the extent that the Company owns or is assigned or licenses patent rights covering its business, third parties may challenge or design around those patent rights, such as by asserting that the patents are invalid or arguing that the patent claims should be narrowly construed, and thereby avoid successful infringement actions.

Our patent applications on MSC technology, in particular, include claims directed to therapeutic uses and kits comprising MSCs. Patents with such claims tend to be more vulnerable to challenge by other parties than patents with extremely narrow claims. Also, our pending patent applications may not issue, may issue with substantially narrower claims than currently pending claims, or we may not receive any additional patents. Further, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. Our patents might not contain claims that are sufficiently broad to prevent others from practicing our technologies or from competing with us with their own technology in the fields of interest to us.

Although the Company has obligations of assignment and has been assigned patents and patent applications concerning stem cell products and their uses, none of those patents or presently pending applications has granted claims or pending claims that, if granted, would absolutely prevent a third party from commercializing their own allogeneic stem cell therapy for those indications that we are studying. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property.

Control over patented technology requires the Company to obtain formal assignment of patents and applications from third parties. Although the Company believes it has contracts requiring formal assignment of the patent properties in its patent portfolio, there is risk that the inventors and research partners now of record as owning these patent properties will refuse to execute documents confirming assignment of their rights to the Company or that litigation will be required to compel the execution of those documents. In the meantime, those inventors and research partners may claim to be co-owners of some of the patent portfolio.

Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our investigational product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. To the extent our investigational product candidates based on that technology are not commercialized ahead of this patent expiration, to the extent we have no other patent protection on such products, or to the extent that regulatory or patent extensions are not granted, those future products might not have the robust protection we currently expect to enjoy. The background technologies used in the development of our investigational product candidates are known in the scientific community, and it may be possible to duplicate the methods we use to create our investigational product candidates, which makes us vulnerable to competition, without the ability to exclude others from potentially commercializing a similar product.

If certain license agreements are terminated, our ability to continue clinical trials and commercially market products could be adversely affected.

We are a party to various agreements that give us rights to use specified technologies applicable to research, development, and commercialization of our investigational product candidates. If these agreements are voided or terminated, our product development, research, and commercialization efforts may be altered or delayed. Certain aspects of our technology rely on inventions developed using university or other third-party resources. The universities or third parties may have certain rights, as defined by law or applicable agreements, and may choose to exercise such rights. If we fail to comply with any terms or provisions of these agreements, our rights and our access to the universities' or third parties' resources could be terminated. The Exclusive License Agreement with the University of Miami dated November 20, 2014, as amended on December 11, 2017, and on March 3, 2021, and the additional Exclusive License Agreement with the University of Miami, signed and effective as of July 18, 2024, require the Company to pay fees and royalties and to make commercially reasonable efforts to achieve milestones. The University of Miami may terminate the Exclusive License Agreement and the additional Exclusive License Agreement for material breach if the fees and royalties are not paid, or if the milestones are not met and an extension to achieve the milestones is not agreed upon.

Some of our employees, including but not limited to Dr. Hare, are employed by third party employers in addition to being employed or engaged as a consultant by the Company. Such employees and consultants may owe obligations to the third-party employers related to that employment. Those third-party employers may assert that they are entitled

to assignment of some or all rights of new inventions made by such employees or consultants. If we are unable to conclusively prove that we are entitled to assignment of those rights, we may be required to negotiate co-ownership to or a license of those rights, if such an arrangement is available at all.

If we are unable to protect the confidentiality of our proprietary information, trade secrets, and know-how, our competitive position could be impaired and our business, financial condition, results of operations, and prospects could be adversely affected.

As disclosed above, some aspects of our technology, especially regarding manufacturing processes, are unpatented and maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators, and advisors to execute confidential disclosure agreements before the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators, or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets could impair our competitive position and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement may prevent or delay our product development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our investigational product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our investigational product candidates, methods of making investigational product candidates, and methods of using investigational product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us. We are aware of several U.S. patents held by third parties covering potentially similar or related products and their manufacture and use. Generally, conducting clinical trials and other acts relating to FDA approval are not considered acts of infringement in the U.S. If and when laromestrocel MSCs are approved by the FDA, third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. We may not be able to prove in litigation that any patent enforced against us is invalid.

Additionally, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our investigational product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our investigational product candidates may infringe. Some of those patent applications may not yet be available for public inspection. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our investigational product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the investigational product candidates unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the

holders of any such patent may be able to block our ability to develop and commercialize the investigational product candidate unless we obtained a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our investigational product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our investigational product candidates. They might seek an exclusion order from the International Trade Commission to prevent import of our investigational product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing investigational product candidates or future products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our investigational product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our investigational product candidates, which could harm our business significantly.

We may become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time-consuming.

Litigation may be necessary to enforce patents issued or licensed to us, to protect trade secrets or know-how, or to determine the scope and validity of the proprietary rights. Litigation, opposition, or other patent office proceedings could result in substantial additional costs and diversion of management focus. If we are ultimately unable to protect our technology, trade secrets, or know-how, we may be unable to operate profitably. Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to protect our proprietary rights, which can be expensive and time-consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or is unenforceable, or may refuse to enjoin the other party from using the technology at issue. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly. Litigation or other patent office proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

Furthermore, though we could seek protective orders where appropriate, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our Class A common stock could be significantly harmed.

Our industry is highly competitive and subject to significant or rapid technological change.

The biotechnology industry, including our fields of therapeutic interest, is highly competitive and subject to significant and rapid technological change. Accordingly, our success may depend, in part, on our ability to respond quickly to such change through the development and introduction of new products. Our ability to compete successfully against currently existing and future alternatives to our investigational product candidates and systems and competitors who compete directly with us in the biopharmaceutical industry may depend, in part, on our ability to attract and retain skilled scientific and research personnel, develop technologically superior products, develop competitively priced products, obtain patent or other required regulatory approvals for our investigational product

candidates, be an early entrant to the market and manufacture, market, and sell products, independently or through collaborations. If a third party were to commercialize a competitive product, there is no assurance that we would have a basis for initiating patent infringement proceedings or that, if initiated, we would prevail in such proceedings.

If our investigational product candidates are approved by the FDA, then potential competitors who seek to introduce generic versions of our investigational product candidates may seek to take advantage of the abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with our investigational product candidates. The Biologics Price Competition and Innovation Act of 2009 might permit these potential competitors to enter the market using a shorter and less costly development program for a biosimilar product that competes with our products. As discussed, our ability to obtain one or more types of regulatory exclusivity upon future product approval could impact the timing of approval of a competing biosimilar or interchangeable product.

If all of the Company's intellectual property has not been properly assigned to the Company, our business, financial condition, results of operation, and prospects could be adversely affected.

While the Company believes that each patent application or patent has already been assigned or, if it has not yet been formally assigned, is under an obligation to be assigned to the Company either through direct employment agreements between the Company and the inventors, or through research agreements with a third party and the Company, if such is not the case, our business, financial condition, results of operations, and prospects could be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our investigational product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- some or all of our licensors' pending patent applications may not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- 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 or in commercial markets where we do not have patent rights;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing

investigational product candidates, future products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our Class A common stock may decline. Such announcements could also harm our reputation or the market for our investigational product candidates and future products which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the U.S. transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of that we also made even if we had made the invention before the invention was made independently by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our investigational product candidates or (2) invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review (PGR), *inter partes* review (IPR), and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in U.S. federal courts, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a patent 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 the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of any resulting issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on

decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

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

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, are limited. Even if patents directed to our investigational product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of investigational product candidates, patents directed to our investigational product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we or our licensors do not obtain patent term extension for our investigational product candidates and/or methods of their use, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our investigational product candidates and their methods of use, one or more of our U.S. patents may be eligible for limited patent term restoration. These laws permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the patent term lost 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 product 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 investigational product candidates. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Patent term extension may also not be granted because the investigational product candidates and/or methods of use are determined not to be the first permitted marketing or use of those drug candidates in the jurisdiction in question, or patent term extension may not be granted because the investigational product candidates and/or methods of use are determined not to constitute an "active ingredient" or use of an "active ingredient" that is eligible for patent term extension. Moreover, if patent term extension is granted then the additional time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Although we have in-licensed issued patents and pending patent applications in the U.S. and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our in-licensed inventions in all countries outside the U.S. or from selling or importing products made using our in-licensed inventions in and into the U.S. or other jurisdictions. Competitors may use our in-licensed technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection but enforcement is not as strong as that in the U.S. These products may compete with our investigational product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our or our licensors' patents or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our or our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensors' patents at risk of being invalidated or interpreted narrowly and our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our or our licensors' efforts to enforce or defend our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental 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 governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has been granted. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business, financial condition, and results of operations. One such compulsory licensing regime arises in the United States; for inventions subject to the Bayh-Dole Act (a/k/a the Patent and Trademark Law Amendments Act, Pub. L. 96-517, December 12, 1980), the United States government may have license rights in those inventions, and may exercise "march in" rights that would grant licenses to third parties to use patents for subject inventions. To date the United States has not exercised "march in" rights under the Bayh-Dole Act, but there is no guarantee that it will not exercise those rights in the future. The United States may also, but rarely does, use patented inventions pursuant to 28 U.S.C. § 1498(a), for which use some compensation would be paid to the Company.

Risks Related to Regulatory Approval and Other Government Regulations

We are substantially dependent on the successful development, regulatory approval and commercialization of laromestrocel, and we cannot assure you that we will obtain regulatory approval or successfully commercialize this investigational therapy.

We are a clinical-stage biotechnology company and currently have no products approved for commercial sale. Our business is substantially dependent on the successful clinical development, regulatory approval and commercialization of laromestrocel, our investigational allogeneic bone marrow-derived mesenchymal stem cell therapy. If laromestrocel fails to demonstrate sufficient safety, efficacy or durability of effect in our ongoing or future clinical trials, including our pivotal studies, or if we are unable to obtain regulatory approval in the United States or other jurisdictions, our business, financial condition and results of operations would be materially adversely affected.

Clinical development is inherently uncertain and subject to significant risk. Results from earlier-stage studies may not be predictive of results in later-stage or larger clinical trials. Regulatory authorities, including the FDA, may disagree with our interpretation of clinical data, our selection of endpoints, the statistical analysis plan, the adequacy of manufacturing controls, or the overall benefit-risk profile of laromestrocel. Even if our pivotal trial meets its primary endpoints, regulatory agencies may require additional clinical trials, longer follow-up, manufacturing comparability data, or other studies before granting approval.

In addition, as a cell-based therapy, laromestrocel presents unique manufacturing, quality control, supply chain, and scalability challenges. We must demonstrate consistent product characterization, potency, sterility, and reproducibility across manufacturing batches. Any failure to meet regulatory requirements for chemistry, manufacturing and controls (CMC), or to establish adequate manufacturing capacity for commercial scale, could delay or prevent regulatory approval.

Even if regulatory approval is obtained, we may encounter challenges in achieving reimbursement, market acceptance, physician adoption, or competitive positioning. If we are unable to successfully commercialize laromestrocel, we may not generate sufficient revenues to sustain operations, which could require us to seek additional financing, enter into strategic transactions, or significantly curtail or discontinue development programs.

Because laromestrocel is currently our primary development asset, any material setback in its development would have a disproportionate impact on our Company.

If we are not able to successfully develop and commercialize our investigational product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations.

To generate sales revenue from our investigational product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate that our investigational product candidates are safe and effective, and we must obtain required regulatory approvals. We may need to devote significant additional research and development, financial resources, and personnel to develop commercially viable products. If our investigational product candidates do not prove to be safe and efficacious in clinical trials, we will not obtain the required regulatory approvals. If we fail to obtain such approvals, we may not generate sufficient revenues to continue our business operations.

We cannot market and sell our investigational product candidates in the U.S. or in other countries if we fail to obtain the necessary regulatory approvals, which are subject to significant uncertainty and may be delayed or never obtained.

We cannot commercialize laromestrocel or any of our other investigational product candidates until we obtain marketing approval from the U.S. FDA or other applicable regulatory authorities. The process of obtaining regulatory approval is lengthy, costly, and inherently uncertain. It typically requires the successful completion of extensive preclinical studies and clinical trials, as well as compliance with rigorous chemistry, manufacturing and controls (CMC) requirements. Regulatory authorities may delay, limit, or deny approval for many reasons, including safety concerns, insufficient efficacy data, manufacturing deficiencies, changes in regulatory standards, or disagreements regarding study design, endpoints, or statistical analyses.

Although we are currently focused on obtaining regulatory approval in the United States, we may pursue approval in additional jurisdictions, including the European Union, Canada, and other international markets. Regulatory requirements outside the United States may differ substantially from those of the FDA and may involve additional clinical data, longer review timelines, local manufacturing requirements, pricing approvals, or country-specific post-approval obligations. The regulatory pathway for advanced therapy medicinal products (ATMPs), including mesenchymal stem cell therapies such as laromestrocel, may be more complex and less predictable than for conventional small-molecule drugs or biologics. If we are unable to successfully navigate these international regulatory frameworks, our ability to expand globally and generate revenues may be materially adversely affected.

In addition, because our investigational product candidates are derived from a limited number of underlying platform technologies, including mesenchymal stem cell — based approaches, any safety signal, manufacturing issue, or regulatory concern arising in one program could negatively impact the development, regulatory review, or approval prospects of our other programs, even if such programs target different indications.

Changes in regulatory laws, policies, or guidance — whether in the United States or internationally — during the course of development or review could result in delays, additional requirements, increased costs, or denial of approval. If we fail to obtain regulatory approvals for laromestrocel or any of our other investigational product candidates, we will be unable to commercialize those products and may not generate sufficient revenue to sustain our operations.

If we are not able to conduct our clinical trials properly and on schedule, marketing approval by the FDA and other regulatory authorities may be delayed or denied.

The completion of our clinical trials may be delayed or terminated for many reasons, including, but not limited to, if:

- the FDA does not grant INDs to test the investigational product candidates in humans;
- the FDA does not grant, or suspends, permission to proceed with a clinical trial and places a trial on clinical hold;
- we are not able to identify sufficient clinical trial sites and/or clinical trial investigators to begin or complete a trial;
- subjects do not enroll in our trials at the rate we expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, cGCPs, cGMPs, Current Good Tissue Practices (cGTPs), and other regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- third-party service providers acting as our local representative in communications with foreign regulatory authorities do not appropriately perform the services required or terminate a service agreement;
- inspections by the FDA or IRBs of clinical trial sites at research institutions participating in our clinical trials find regulatory violations that require us to undertake corrective action, suspend, or terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications; or
- one or more IRBs suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial.

Our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate, or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval for our investigational product candidates may be delayed or denied by the FDA.

Even if we complete clinical development, regulatory approval may be delayed, limited, or subject to burdensome conditions, which could materially affect our commercial prospects.

Even if our clinical trials for laromestrocel or other investigational product candidates are successfully completed, regulatory approval may be delayed, limited to narrower indications than requested, or conditioned upon additional post-marketing requirements. The FDA or other regulatory authorities may determine that our data are insufficient to support approval for the full patient population studied, may require additional clinical trials, extended follow-up, or real-world evidence, or may impose restrictions on labeling, distribution, or manufacturing.

Regulatory authorities may also issue a Complete Response Letter (CRL) identifying deficiencies in our marketing application that require substantial additional work, including new clinical trials or manufacturing remediation efforts. In addition, the FDA may refuse to file our application if it determines that it is incomplete or does not meet filing requirements.

Even if approval is granted, regulatory authorities may require post-marketing commitments, REMS, manufacturing inspections, or other conditions that could limit commercial uptake or increase costs. Any delay, limitation, or denial of approval could materially adversely affect our ability to generate revenues and achieve profitability.

Alzheimer's disease drug development has historically had a high rate of failure, and we may not be successful in developing an effective therapy for this indication.

Alzheimer's disease ("AD") has proven to be one of the most challenging therapeutic areas in biopharmaceutical development. Despite substantial industry investment over several decades, there have been relatively few regulatory approvals, and many investigational therapies have failed in late-stage clinical trials due to lack of efficacy or safety concerns.

While certain amyloid beta — directed antibodies have received FDA approval, including under accelerated approval pathways based on surrogate biomarkers, the long-term clinical benefit, reimbursement landscape, and broader regulatory standards in AD continue to evolve. The use of surrogate endpoints, such as amyloid reduction, remains subject to ongoing scientific and regulatory debate, and confirmatory trials are required to verify clinical benefit. There can be no assurance that regulatory authorities will accept the endpoints, trial designs, or magnitude of effect demonstrated in our studies as sufficient to support approval.

Numerous therapeutic approaches have been evaluated in AD, including monoclonal antibodies, secretase inhibitors, BACE inhibitors, RAGE inhibitors, receptor modulators, and other novel mechanisms. The majority of these programs have not successfully demonstrated clinically meaningful benefit. As a result, regulatory agencies may apply heightened scrutiny to investigational therapies in AD.

Our investigational programs in AD are at an early stage of development. We have not yet demonstrated that our therapeutic approach will produce meaningful clinical outcomes or receive regulatory approval. If our clinical trials fail to demonstrate safety and efficacy, or if regulatory authorities determine that our data are insufficient to support approval, our ability to commercialize an AD therapy would be materially adversely affected.

Our business involves the use of hazardous materials that could expose us to environmental and other liability.

We have contract facilities in Florida that are subject to various local, state, and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms, and various radioactive compounds used in connection with our research and development activities. In the U.S., these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act, and the Resource Conservation and Recovery Act. We cannot guarantee that accidental contamination or injury to our employees and third parties from hazardous materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

Our CMC readiness and ability to manufacture laromestrocel for commercialization and any future product candidates for clinical or commercialization may require significant additional investment, be delayed or be unsuccessful.

Our BLA-enabling activities, including comparability protocols, process and analytical method validation are complex and subject to regulatory review. Any delays or failures in these activities could impact our ability to meet regulatory and investor expectations for product approval or commercial launch of our investigational product candidates. Our ability to complete BLA-enabling activities may impact the clinical and commercial success of our current and any future investigational product candidates. In addition, the FDA or other relevant regulatory authorities may find our CMC data insufficient to support the quality of our investigational product candidates. The FDA's approval of a BLA is not guaranteed, and the review and approval process is expensive, uncertain and may take several years. The FDA also has substantial discretion in the approval process. These matters are subject to confirmation and interpretation by regulatory authorities, which could delay, limit, or prevent regulatory approval. Our clinical development efforts may fail at any stage. Our financial condition may be materially adversely affected by any delay or inability to complete our CMC readiness and BLA-enabling activities.

Even if we receive regulatory approval of laromestrocel or any of our other investigational product candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our investigational product candidates.

Any regulatory approvals that we receive for laromestrocel or another product candidate may require post-marketing surveillance to monitor the safety and efficacy of the product and may require us to conduct post-approval clinical studies. The FDA may also require a REMS program in order to approve our investigational product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to assure safe use (ETASU), 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 investigational product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our investigational product candidates will be subject to extensive and ongoing regulatory requirements. These requirements can include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs, for any clinical trials that we conduct post-approval and applicable product tracking and tracing requirements. Compliance with ongoing and changing requirements takes substantial resources and, should we be unable to remain in compliance, our business could be materially and adversely affected.

Manufacturers and their facilities are required to 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 cGMPs and adherence to commitments made in any marketing application, 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 investigational product candidates may be subject to limitations on the approved indicated uses for which the future product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate.

Later discovery of previously unknown problems with our investigational product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, or the making of unsupported claims, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials 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 our future products, withdrawal of the future product from the market or product recalls;
- fines, 483 observations, warning letters, untitled letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our investigational product candidates; and
- consent decrees or injunctions or the imposition of civil or criminal penalties, or the invocation of the FDA's Application Integrity Policy.

Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. Companies may also share certain scientific and medical information about off-label uses of products in certain limited circumstances as part of scientific exchange. However, 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 investigational 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.

Our potency assay strategy may not be accepted by regulatory authorities or may require further development which could delay or prevent approval

Potency assays for cell-based therapies are inherently complex and may be subject to evolving regulatory expectations. Our potency assays must be shown to be representative of the final drug product, stability-indicating, and suitable for lot release and comparability assessments. Regulatory authorities may require additional assay development, qualification, or validation work, or may require us to demonstrate correlation between assay results and clinical outcomes.

If our potency assay strategy is not accepted, or if assay performance proves variable, non-robust, or difficult to transfer between laboratories or manufacturing sites, we may experience delays in clinical development, BLA submission, or product approval, or incur substantial additional costs.

Ongoing healthcare legislative and regulatory reform measures in the U.S. and other countries may have a material adverse effect on our business and results of operations.

In the U.S. and in many foreign jurisdictions, the legislative landscape continues to evolve. Our revenue prospects could be affected by changes in healthcare spending and policies in our target markets. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could materially and adversely affect us.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to labeling for our future products; the recall or discontinuation of our future products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Compliance with the regulatory requirements for biologics and cell and gene therapies can be more burdensome, expensive and time-consuming than for other, better known or more extensively studied types of medicines. Regulatory requirements governing cell and genetic therapy products have changed frequently and may continue to change in the future.

There is significant interest in promoting healthcare reform, as evidenced by the enactment in the U.S. of the ACA in 2010. It is likely that many governments will continue to consider new healthcare legislation or changes to existing legislation. We cannot predict the initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified, or how they may affect us. The continuing efforts of governments, insurance companies, managed care organizations and other third-party payors to contain or reduce healthcare costs may adversely affect:

- the demand for any investigational product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our future approved products;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Since the ACA was enacted, other legislative changes have been proposed and adopted in the United States. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013, and subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2030, unless additional congressional action is taken. However, these Medicare sequester reductions were suspended from May 1, 2020, through December 31, 2022, due to the COVID-19 pandemic. The BBA also amended the ACA,

effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. President Trump recently revoked numerous executive orders issued by President Biden, including executive orders which were designed to further implement the ACA. Litigation and legislation over the ACA is likely to continue, with unpredictable and uncertain results.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our investigational product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

First Trump Administration

At the federal level, the first Trump Administration's budget for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the first Trump Administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The first Trump Administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, Centers for Medicare and Medicaid Services ("CMS") issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders directed the Secretary of HHS to: (1) eliminate protection under an AKS safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of the proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) require Federally Qualified Health Centers, or FQHCs, participating in the 340B drug program to provide insulin and injectable epinephrine to certain low-income individuals at the discounted price paid by the FQHC, plus a minimal administrative fee. On October 1, 2020, the FDA issued the final rule allowing importation of certain prescription drugs from Canada. On August 6, 2020, President Trump signed an additional Executive Order directing U.S. government agencies to encourage the domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, which include among other things, active pharmaceutical ingredients and drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of COVID-19. The FDA was directed to release a full list of Essential Medicines, Medical Countermeasures, and Critical Inputs affected by this Order by November 5, 2020. On September 13, 2020, President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. Although a number of these and other measures may require additional authorization to become

effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Biden Administration

Additionally, on July 9, 2021, former President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition. It is unclear how other healthcare reform measures of the former Biden Administration, the second Trump Administration, or other efforts, if any, to challenge or repeal the ACA will impact our business. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would impact healthcare reform efforts of prior Administrations, affect the demand for our investigational product candidates or future products, or otherwise impact our business. Legislative and regulatory agendas, as they relate to the healthcare and pharmaceutical industries and the economy as a whole, of the second Trump Administration and the U.S. Congress currently remain uncertain. Any new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, such as the proposed cap on CRO indirect cost reimbursements by the National Institute of Health (NIH), or impose additional regulatory requirements on drug development or approval, which could have a material adverse effect on our clinical trial sites that rely on collaborations with university hospitals and research institutions funded in whole or in part by NIH grants, our future customers and accordingly, our financial operations.

Inflation Reduction Act

On August 16, 2022, the Inflation Reduction Act of 2022 was passed, which among other things, allows for CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known. Additionally, it is not yet known whether, during the second Trump Administration, the Inflation Reduction Act of 2022 will be repealed or otherwise further modified. Notably, the OBBBA modifies the drug price negotiation protections enacted under the Inflation Reduction Act of 2022 by expanding the list of drugs exempt from negotiation and delaying the implementation of additional price controls for some products, including drugs and biologics with more than one orphan designation and more than one approved indication. The OBBBA also reduced funding to federal healthcare programs and imposed additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs.

Later, in September 2023, the Federal Trade Commission (FTC) issued a policy statement articulating its view that certain "improper" patent listings by drug developers in FDA's Orange Book represent an unfair trade practice and indicated that industry stakeholders should be prepared for potential enforcement actions based on its analysis. The FTC followed that action in November 2023 by publicly calling out over 100 "improper" patent listings made by ten large pharmaceutical companies and initiating an FDA administrative process with respect to those patents. The controversy regarding the appropriateness of listing such patents has led to numerous lawsuits alleging anticompetitive conduct by biopharmaceutical companies. It remains to be seen whether the FTC under the Trump Administration will continue to prioritize the policy issue of "improper" patent listings or whether Congress may take any legislative actions related to this issue.

Furthermore, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo*, which overturned the long-standing Chevron doctrine that required courts to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes, could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA. The *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rule-making process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges.

Second Trump Administration

Since taking office for his second term, President Trump has issued a number of executive orders that could have a significant impact on the manner in which the FDA, HHS, CMS, and other related agencies conduct their operations, including: on January 31, 2025, which required at least 10 existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation; on February 13, 2025, which established the President's Make America Healthy Again Commission and its initial assessments and reports; on February 21, 2025, which required agency heads to initiate a process to review all regulations subject to their sole or joint jurisdiction for consistency with law and Administration policy and report back a list of all regulations identified by each class described in the executive order within 60 days; on April 15, 2025, outlining several actions the Secretary of the Department of HHS must take to optimize healthcare regulations that will provide access to prescription drugs at lower costs; on May 5, 2025, aiming to promote domestic production of critical medicines; and on May 12, 2025, aiming to establish a "most favored nation" drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. Since the May 12, 2025 "most favored nation" executive order, the Trump Administration has continued to exert pressure on drug manufacturers to implement "most favored nation" pricing, including by suggesting that the administration may impose significant tariffs on pharmaceuticals if such manufacturers do not reach agreements to implement "most favored nation" pricing.

Additionally, on September 9, 2025, the President issued a Memorandum directing HHS to "ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." The same day, the Make America Healthy Again Commission released a report declaring that the FDA, HHS, FTC and Department of Justice (DOJ) "will increase oversight and enforcement under current authorities for violations of direct-to-consumer (DTC) prescription drug advertising laws." To that end, the FDA announced that it is initiating a rulemaking process "to eliminate the 'adequate provision' loophole that allows pharmaceutical advertisements to hide safety information by placing it in another format or location." In this context, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the agency would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA also issued a generic "notice letter" directing companies to "remove any noncompliant advertising and bring all promotional communications into compliance." In November 2025, CMS announced a new voluntary payment initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) where drug manufacturers may voluntarily offer supplemental rebates to participating state Medicaid programs that are intended to provide such Medicaid programs with a "most favored nation" price for participating manufacturers' products.

The current presidential administration aims to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as the FDA, HHS, and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees and operations. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to use of artificial intelligence to review product applications. Additionally, any federal government shutdowns may prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process our regulatory submissions. Any budgetary cut, including those enacted for fiscal year 2026 and in the future, can impact the FDA's ability to approve current or future products and could delay regulatory approval of our current or future product candidates. This could delay commercialization of our products.

On February 17, 2025, the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP), chaired by Senator Bill Cassidy (R-LA), published a white paper outlining proposed reforms to the U.S. FDA. Developed with input from patient advocates, researchers, clinical societies, and manufacturers, the report proposes areas where FDA's regulatory framework may be strengthened to accelerate patient access to safe and effective products. The report's recommendations span FDA's full regulatory scope:

- extending the "least burdensome" principle beyond medical devices;
- piloting a notification pathway for Phase I trials;

- creating an intermediate biologics approval pathway;
- simplifying interchangeability and biosimilar study requirements;
- codifying tailored CMC requirements for small-population therapies;
- improving review predictability and judicious use of clinical holds;
- updating device review pathways for software;
- aligning CDS guidance with the 21st Century Cures Act;
- modernizing GRAS review; and
- evaluating the effectiveness of the Food Safety Modernization Act.

Although these changes to FDA's regulatory framework ostensibly are intended to accelerate market access to various products, including biologics and biosimilars, the implementation of these changes can take years and any changes to the current regulatory framework could impact or delay the review and approval of our investigational product candidate while the changes are being implemented.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our future products, once approved, or put pressure on our product pricing.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our investigational product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. We are unable to predict what healthcare programs and regulations will ultimately be implemented at any level of government in or outside the U.S., but any changes that decrease reimbursement for our future approved products, reduce volumes of medical procedures or impose new cost-containment measures could adversely affect us.

Risks Related to Our Dependence on Third Parties

We rely on third parties to serve as local representatives in foreign jurisdictions where we perform our clinical trials.

We rely on third parties to provide us with services related to our clinical trials conducted domestically and in foreign jurisdictions. In foreign jurisdictions, such third parties may serve as our local representative. Such local representative may perform services that include corresponding with the foreign regulatory authority on our behalf. If such third party fails to comply with applicable laws, misrepresents our intentions, fails to adequately provide the necessary services, or terminates its relationship with us, our clinical trial process may be delayed as we engage a new service provider, which would increase our anticipated development and commercialization costs. Any prolonged disruption could have a significant negative impact on our ability to effectively communicate with regulatory authorities, which could delay our pre-clinical and clinical trials.

We rely on third parties to provide us with supplies to produce our investigational product candidates. Any problems experienced by these third parties could result in a delay or interruption in the supply of our investigational product candidates for our clinical trials and future approved products to our customers, which could have a material negative effect on our business.

We rely on third parties to provide us with supplies to produce our investigational product candidates. If the operations of these third parties are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill our supply of investigational product candidates. Any prolonged disruption in the operations of third parties could have a significant negative impact on our ability to produce our investigational product candidates for pre-clinical and clinical trials or sell our future approved products, could harm our reputation and could cause us to seek other third-party contracts, thereby increasing our anticipated development and commercialization costs. In addition, if we are required to change third parties for any reason, we will be required to verify that the new third parties maintain facilities and procedures that comply with quality standards required by the FDA and with all applicable regulations and guidelines. The delays associated with the qualification of a new third party could negatively affect our ability to develop investigational product candidates or receive approval for any investigational product candidates in a timely manner.

We currently depend upon third parties for services and raw materials needed for the manufacture of our investigational product candidates, and if these products are successfully commercialized, we may become dependent upon third parties for product distribution. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver could be compromised.

To produce our investigational product candidates for use in clinical studies, and to produce any of our investigational product candidates that may be approved for commercial sale, we require biologic media, reagents, and other highly specialized materials in addition to the bone marrow aspirate used in the manufacture of our investigational product candidates. These items must be manufactured and supplied to us in sufficient quantities and in compliance with the regulations governing cGMP and cGTP promulgated by the FDA. To meet these requirements, we have entered into supply agreements with firms that manufacture these components to meet cGMP and cGTP standards. Our requirements for these items are expected to increase if and when we transition to the manufacture of commercial quantities of our investigational product candidates.

In addition, as we proceed with our clinical trial efforts, we must be able to demonstrate to the FDA that we can manufacture our investigational product candidates with consistent characteristics. While we currently produce our investigational product candidates in our own facility, scaling up the manufacturing process would require us to develop a larger facility, which could require significant time and capital investments to conform to applicable manufacturing standards. Alternatively, we may be required to outsource some or all of our manufacturing, which would cause us to be materially dependent on these suppliers for supply of cGMP- and cGTP-grade components of consistent quality. Our ability to complete ongoing clinical trials may be negatively affected in the event that we are forced to seek and validate a replacement source for any of these critical components. If we are not able to obtain adequate supplies of these items of consistent quality from our third-party suppliers, it will also be more difficult to manufacture commercial quantities of our investigational product candidates that are approved for commercial sale.

In addition, if one or more of our investigational product candidates is approved for commercial sale, we intend to rely on third parties for their distribution. Proper shipping and distribution require compliance with specific storage and shipment procedures (e.g., prevention of damage to shipping materials and prevention of temperature excursions during shipment). Failure to comply with such procedures will necessitate return and replacement, potentially resulting in additional cost and causing us to fail to meet supply requirements.

Our reliance on third-party manufacturers and technology transfer activities introduces additional CMC and regulatory risk.

We may rely in part on third-party contract development and manufacturing organizations (“CDMOs”) for manufacturing, testing, storage, or distribution of our investigational product candidates. Technology transfer of manufacturing processes, analytical methods, or quality systems to a CDMO is complex and may result in delays, deviations, or failures to reproduce product quality attributes.

Any failure by a CDMO to comply with cGMP requirements, successfully complete validation activities, pass regulatory inspections, or meet contractual obligations could delay our development programs, require remediation or replacement of the CDMO, or adversely impact our ability to obtain or maintain regulatory approval.

Regulatory inspections of our facilities or those of our third-party manufacturers could result in findings that delay or prevent approval.

Our manufacturing facilities and those of our third-party manufacturers are subject to pre-approval inspections and routine regulatory inspections. Any inspectional observations, warning letters, or findings of non-compliance with cGMP requirements could require corrective and preventive actions, restrict manufacturing operations, delay approval of our applications, or result in enforcement actions, including clinical holds or withdrawal of approval.

Use of third-party manufacturers may increase the risk that we will not have adequate quantities of our investigational product candidates.

We may use a third-party manufacturer to supply our investigational product candidates for clinical trials or other uses at some point. Reliance on third-party manufacturers involves risks to which we would not be subject if we manufactured the investigational product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, possible breach of the manufacturing agreement by the third party or termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Future contract manufacturers are or will be subject to all of the risks and uncertainties that we would be subject to if we manufactured the investigational product candidates on our own. Similar to us, third-party manufacturers are subject to ongoing, periodic, and unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP and cGTP regulations and other governmental regulations and corresponding foreign standards. Although we do not control compliance by our contract manufacturers with these regulations and standards, we — as the manufacturer — assume the liabilities for our contract manufacturers' non-compliance. Our future contract manufacturers might not be able to comply with these regulatory requirements. If our third-party manufacturers fail to comply with applicable regulations, the FDA or other regulatory authorities could impose penalties on us, including fines, injunctions, civil penalties, consent decrees, invocation of FDA's Application Integrity Policy, issuance of warning or untitled letters, denial of marketing approval of our investigational product candidates, delays, suspensions, or withdrawals of approvals, license revocation, seizures or recalls of investigational product candidates or our other future products, operating restrictions, and criminal prosecutions. Any of these actions could significantly and adversely affect supplies of our investigational product candidates or other future products and could have a material adverse effect on our business, financial condition, and results of operations.

We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential investigational product candidates.

We depend, or may depend in the future, upon third parties to conduct certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely especially heavily on universities, medical institutions, CROs and other third parties for the conduct of our clinical trials. While we are obligated to ensure compliance of third parties with our clinical trial protocols and other aspects of our clinical trials, and to have mechanisms in place to monitor our clinical trials, the sites at which they are conducted, and the investigators and other personnel involved in our clinical trials, we have limited control over these entities and individuals and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Our reliance on third parties does not relieve us of our regulatory responsibilities for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with cGCP requirements, for investigational product candidates in clinical development. Regulatory authorities enforce cGCP

requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with cGCP requirements.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients meeting requirements for enrollment in the trial may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if, due to federal or state orders, they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our investigational product candidates. As a result, our financial results and the commercial prospects for our investigational product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar 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.

Because we have made a strategic decision to use third-party manufacturers in the future, they will likely be dependent upon their own third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

The operations of any future third-party manufacturers will likely be dependent upon their own third-party suppliers. A supply interruption or an increase in demand beyond a supplier's capabilities could harm the ability of any future manufacturers to manufacture our investigational product candidates or future approved products until the manufacturer identifies and qualifies new sources of supply. Reliance on these third-party manufacturers and their suppliers could subject us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- failure of third-party manufacturers or suppliers to comply with their own legal and regulatory requirements;
- delays in future product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner;

- production delays related to the evaluation and testing of future products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to suppliers prioritizing other customer orders over ours or those of our third-party manufacturers;
- damage to our brand reputation caused by defective components produced by the suppliers; and
- fluctuation in delivery by the suppliers due to changes in demand from us, our third-party manufacturers or their other customers.

Any interruption in the supply of components of our investigational product candidates or future products or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demands of our clinical trials or of our future customers, which would have an adverse effect on our business.

We will depend on third-party distributors in the future to market and sell our future products which will subject us to a number of risks.

We will depend on third-party distributors to sell, market, and service our future products in our intended markets. We are subject to a number of risks associated with reliance upon third-party distributors including:

- lack of day-to-day control over the activities of third-party distributors;
- failure of the third-party distributors to comply with their own legal and regulatory requirements;
- third-party distributors may not commit the necessary resources to market and sell our future products to our level of expectations;
- third-party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us; and
- disagreements with our future distributors could result in costly and time-consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar.

If we fail to establish and maintain satisfactory relationships with our future third-party distributors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which could harm our results of operations and financial condition.

We may engage in future acquisitions, strategic partnerships, mergers, or the sale and/or licensing of our intellectual property, which could disrupt our business, increase our capital requirements, dilute our stockholders, harm our financial condition and operating results, and subject us to other risks.

From time to time, we evaluate various potential acquisition opportunities and strategic partnerships, including the licensing, acquisition, or sale of our investigational product candidates, intellectual property rights, technologies or businesses or complementary products, investigational product candidates, intellectual property rights, technologies or businesses. Any potential acquisition, sale strategic partnership, or licensing arrangement may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products or investigational product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic licensing arrangement, merger or acquisition;

- in the case of a licensing arrangement, counterparties and partners may not properly or adequately obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our intellectual property or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party to receive marketing approvals for their existing products or investigational product candidates; and
- our inability to generate revenue from acquired technology, investigational product candidates and/or approved products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, we may not be able to locate suitable acquisition, merger, or license candidates and we may not be able to complete acquisitions, mergers, or licenses on favorable terms, if at all. If we do complete an acquisition, merger or license, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors, which, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

The successful commercialization of our current or future investigational product candidates will depend on obtaining reimbursement from government and third-party payors, and price controls in foreign markets could adversely affect our future profitability.

If we successfully develop and obtain necessary regulatory approvals, we intend to sell our investigational product candidates in countries such as the U.S. and Japan. In the U.S., the market for any pharmaceutical product is affected by the availability of reimbursement from government and third-party payors, such as government health administration authorities, private health insurers, health maintenance organizations, and pharmacy benefit management companies. MSC therapies may be expensive compared with conventional pharmaceuticals, due to the higher cost and complexity associated with the research, development, and production of investigational product candidates, the small size and large geographic diversity of the target patient population for some indications, and the complexity associated with distribution of signaling cell therapies which require special handling, storage, and shipment procedures and protocols. This, in turn, may make it more difficult for us to obtain adequate reimbursement from government and third-party payors, particularly if we cannot demonstrate a favorable cost-benefit relationship. Government and third-party payors may also deny coverage or offer inadequate levels of reimbursement for our potential products if they determine that the product has not received appropriate clearances from the FDA or other government regulatory authorities or is experimental, medically unnecessary or inappropriate.

In some other countries where we may seek to market our future products, such as Japan, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our potential future collaborators may be required to conduct one or more clinical trials that compare the cost effectiveness of our investigational product candidates or future products to other available therapies. Conducting one or more additional clinical trials would be expensive and could result in delays in commercialization of our investigational product candidates.

Managing and reducing healthcare costs has been of great concern in the U.S. and various foreign governments. Although we do not believe that any recently enacted or presently proposed legislation in any jurisdictions in which we currently operate should impact our business based on our current model, we might be subject to future regulations or other cost-control initiatives that materially restrict the pricing or reimbursement of our future products. In addition, payors are continuing to limit reimbursements for newly approved healthcare products while also challenging the price and cost-effectiveness of medical products and services. In particular, payors may limit the indications for which they will reimburse patients who use any products that we may develop. Finally, cost

control initiatives could decrease the price for products that we may develop, which could result in lower product revenues to us. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

We may enter into arrangements with third-party collaborators to help us develop our investigational product candidates and commercialize our future products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful.

We are parties to various collaborations with third parties, and we may enter into additional collaborations in the future. We are dependent upon the success of our current and any future collaborators in performing their responsibilities in connection with the relevant collaboration. If we fail to maintain these collaborative relationships for any reason, we would need to perform the activities that we currently anticipate would be performed by our collaborators on our own at our sole expense. This could substantially increase our capital needs, and we may not have the capability or financial capacity to undertake these activities on our own, or we may not be able to find other collaborators on acceptable terms, or at all. This may limit the programs we are able to pursue and result in significant delays in the development, sale, and manufacture of our investigational product candidates and future approved products, and may have a material adverse effect on our business, financial condition, and results of operations.

Our dependence upon our current and potential future collaborations exposes us to a number of risks, including that our collaborators (i) may fail to cooperate or perform their contractual obligations, including financial obligations, (ii) may choose to undertake differing business strategies or pursue alternative technologies, or (iii) may take an opposing view regarding ownership of clinical trial results or intellectual property.

Due to these factors and other possible events, we could suffer delays in the research, development, or commercialization of our investigational product candidates and future approved products or we may become involved in litigation or arbitration, which could be time consuming and expensive. We additionally may be compelled to split revenue with our collaborators, which could have a material adverse effect on our business, financial condition, and results of operations.

Our employees, principal investigators, CROs and consultants 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 that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct, or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third-parties, 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 governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Risks Related to the Discovery, Development and Commercialization of Our Investigational Product Candidates

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data. These results and related findings and conclusions are based on assumptions, estimations, calculations and conclusions, and are subject to change following the generation of additional data or a more comprehensive review of the data related to the particular study or trial. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data is available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. For example, we have reported interim data from our ongoing clinical trials elsewhere in this report. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available or as subjects from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Class A common stock.

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

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our investigational product candidates may be harmed, which could have a material adverse effect on our business, financial condition, and results of operations.

We may expend our limited resources to pursue a particular investigational product candidate or indication and fail to capitalize on other investigational 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 investigational product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or investigational product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. 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, therapeutic platforms and investigational 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.

The U.S. FDA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We are conducting several trials in the U.S., and previously entered into a sponsored clinical research agreement with the National Center for Geriatrics and Gerontology and Juntendo University Hospital in Japan to explore the safety and efficacy of laromestrocel in older, frail Japanese subjects. This study in Japan was discontinued by the Company in 2024. The acceptance of study data by the U.S. FDA, Japanese PMDA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U.S. population and U.S. medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to cGCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means. The FDA may accept the use of some foreign data to support a marketing approval if the clinical trial meets certain requirements. Additionally, the FDA's clinical trial requirements, including the adequacy of the subject population studied and statistical powering, must be met. Furthermore, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, PMDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its respective jurisdiction. If the FDA, PMDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our investigational product candidates not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of a product in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of a product in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or PMDA grants marketing approval of an investigational product candidate, comparable regulatory authorities in other foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the investigational product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Moreover, product types or regulatory classifications, as well as approval procedures, vary among jurisdictions and can involve requirements and administrative review periods different from those in the U.S., including different or additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product 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 future products is also subject to approval.

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

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

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

If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our investigational product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic test, we will not be able to commercialize such future approved product and our ability to generate revenue will be materially impaired.

If safe and effective use of any of our investigational product candidates depends on the use of an *in vitro* diagnostic test that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our investigational product candidates if at all. According to FDA guidance, if the FDA determines that a companion diagnostic is essential to the safe and effective use of a novel therapeutic product or indication, then the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to its own regulatory approval requirements. The process of obtaining or creating such a diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities. The approval of a companion diagnostic as part of the therapeutic product labeling limits the use of the therapeutic product to only certain patients for whom the companion diagnostic was developed.

If the FDA, PMDA or a comparable regulatory authority requires approval of a companion diagnostic for any of our investigational product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of an investigational product candidate or continued marketing of a future approved product.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials of a product candidate or commercializing a future approved product on a timely or profitable basis, if at all.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through an expedited review program, and if we are unable to do so, then we could face increased expense to obtain, and delays in the receipt of, necessary marketing approvals.

We may in the future seek approval for one or more of our investigational product candidates under one of the FDA's expedited review programs for serious conditions. These programs are available to sponsors of therapies that address an unmet medical need to treat a serious condition. The qualifying criteria and requirements vary for each expedited program. Prior to seeking review under one of these expedited programs for any of our investigational product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive marketing approval through an expedited review program.

There can be no assurance that, after our evaluation of the FDA's feedback and other factors, we will decide to pursue one or more of these expedited review programs. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue one or more of these expedited programs, even if we initially decide to do so. Furthermore, the FDA could decide not to grant our request to use one or more of the expedited review programs for an investigational product candidate, even if the FDA's initial feedback is that the product candidate would qualify for such program(s). Moreover, the FDA can decide to stop reviewing a product candidate under one or more of these expedited review programs if, for example, the conditions that warranted expedited review no longer apply to that product candidate.

Some of these expedited programs (e.g., accelerated approval) also require post-marketing clinical trials to be completed and, if any such required trial fails, the FDA could withdraw the approval of the product. If one of our investigational product candidates does not qualify for any expedited review program, then this could result in a longer time period to approval and commercialization of such product candidate, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

The FDA's Rare Pediatric Disease Designation for laromestrocel for HLHS does not guarantee that we will receive a priority review voucher if the product is approved for this indication, nor does the receipt of Orphan Drug Designation for laromestrocel for HLHS guarantee that we will receive seven years of market exclusivity if the product is approved for this indication.

As noted elsewhere in this report, the FDA has granted both Rare Pediatric Disease Designation and Orphan Drug Designation status for the use of laromestrocel to treat HLHS. These designations were granted following our Phase 1 safety-focused ELPIS trial, However, even though the FDA has granted laromestrocel Rare Pediatric Disease Designation for the treatment of HLHS, receipt of Rare Pediatric Disease Designation does not provide any guarantee that we would or will receive a priority review voucher (PRV) upon approval for this indication. The Consolidated Appropriations Act of 2026, signed into law on February 3, 2026, extended the PRV program through September 2029. If we do receive a PRV upon approval of laromestrocel for this indication, then that voucher permits a future application to be treated as a priority review application by the FDA. The FDA does not guarantee that the future application will be reviewed in a particular period of time, and a future application that redeems a PRV must submit an additional user fee in addition to any regularly assessed user fees. Vouchers may be transferred, including by sale; accordingly, there is a market for these vouchers at prices that have historically fluctuated. If we receive a voucher, we cannot guarantee that we will use it or that there will be a market to transfer or sell the voucher. Further, receipt of Orphan Drug Designation does not guarantee that we will receive seven years of market exclusivity upon approval for this indication unless all appropriate statutory and regulatory criteria are met, the interpretation of which, as noted, has been in flux. Orphan Drug designation can also be rescinded in specific circumstances and, if the designation is withdrawn after drug approval, any orphan drug exclusivity awarded would be rescinded as well.

The FDA has also granted Fast Track Designation to laromestrocel for the treatment of HLHS. A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not necessarily increase the likelihood that our investigational product candidates will receive marketing approval for this indication.

The FDA's RMAT and Fast Track designations for laromestrocel for mild AD does not guarantee that laromestrocel will be developed or approved faster, or more successfully, than if these designations were not granted, and FDA could rescind these designations if the qualifying criteria are no longer met.

The FDA has granted two designations to laromestrocel for the treatment of mild AD based on the completion of certain clinical trials: RMAT Designation and Fast Track Designation. RMAT Designation may be granted to a regenerative medicine therapy, including a cell therapy, that is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. An RMAT Designation can provide earlier and more intensive interactions with FDA during the drug development process. However, these interactions may not lead to a faster or more successful laromestrocel development program or approval for mild AD because FDA review priorities may change, or the designation could be withdrawn if the qualifying criteria for RMAT Designation are no longer met.

FDA has also granted Fast Track Designation to laromestrocel for the treatment of mild AD. Products are eligible for this designation if they are intended to treat a serious or life-threatening disease or condition, and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Benefits of a Fast Track Designation can include more frequent interactions with FDA, as well as rolling review of portions of an application before the complete application is submitted. However, a Fast Track Designation does not guarantee that we will have a faster or more successful laromestrocel development program or approval for mild AD because FDA review priorities may change, or the designation could be withdrawn if the qualifying criteria for Fast Track Designation are no longer met.

We may face difficulties from changes to current regulations and future legislation, both in the U.S. as well as in other foreign jurisdictions where we may be operating.

As referenced above, existing regulations and regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our investigational 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 U.S. 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.

Our relationships with healthcare professionals, clinical investigators, CROs and payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and payors play a primary role in the recommendation and prescription of any investigational product candidates for which we obtain future marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our future products for which we obtain marketing approval. Although our investigational product candidates are not currently reimbursed by government healthcare programs such as Medicare or Medicaid, any future reimbursement of our future approved products from federal and/or state healthcare programs could expose our business to broadly applicable fraud and abuse laws and other healthcare laws and regulations that would regulate the business. Restrictions under applicable federal and state healthcare laws and regulations, as set forth above.

In addition, the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments

and other transfers of value to physicians, certain other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported will be publicly available on a searchable website, with disclosure required annually.

Further, some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Further state laws require biotechnology companies to report information on the pricing of certain drug products. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, as previously stated, the collection and use of health data in the EU is governed by the GDPR, which extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, temporary or permanent debarment, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

A variety of factors, including inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, collection of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result of these and other factors. In particular, the FDA has relatively limited experience with regulating novel investigational product candidates like ours, and this may add to its already fluctuating review times. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new investigational product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, (including, most recently February 2026) and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Recently, in April 2025, the U.S. Department of Health and Human Services (HHS) initiated a significant reduction in force (RIF), impacting roughly 3,500 FDA employees — about 19% of the agency — as part of a broader 10,000-person layoff across HHS agencies. These cuts, aimed at

restructuring and reducing bureaucracy, largely targeted administration, policy, and communications. While major product reviewers and inspectors were reportedly spared, the cuts disrupted administrative support for application reviews and inspections, as well as Advisory Committee meetings. Apart from the RIFs, a significant number of FDA employees have also resigned from the agency during this time. Among these departures was Dr. Peter Marks, the Director of the Center for Biologics Evaluation & Research, which is the center to whom our application would be submitted. The reduction in workforce and loss of institutional knowledge from the agency could impact and, in fact, already has impacted the FDA's capacity to process applications, conduct inspections, meet review goals/deadlines, and enforce regulatory standards, which may, in turn, influence the regulatory environment in which our company operates. While the full implications of the FDA's RIF and resignations remain uncertain, any decrease in FDA staffing levels could lead to delays in review times, increased backlog of applications, or changes in regulatory priorities. Such developments could potentially affect our product approvals, compliance obligations, or timing of regulatory actions, thereby impacting our operations, financial condition, and results of operations.

Separately, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold in connection with the COVID-19 pandemic, the FDA has been working to resume pre-pandemic levels of inspections, including routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel or for other reasons, and the FDA does not determine that a remote interactive evaluation will be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to a pandemic and may experience delays in their regulatory activities.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

We may not be successful in our efforts to identify or discover additional investigational product candidates in the future.

Our research programs may initially show promise in identifying potential investigational product candidates, yet fail to yield viable investigational product candidates for clinical development for a number of reasons, including:

- our inability to design such investigational product candidates with the pharmacological properties that we desire or that result in attractive pharmacokinetics;
- our inability to design and develop a suitable manufacturing process; or
- potential investigational product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance.

Research programs to identify new investigational product candidates require substantial technical, financial and human resources. If we are unable to identify other suitable treatments for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we further expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. In recent years, the SEC and Department of Justice (DOJ) have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. On February 10, 2025, President Trump signed an executive order titled "Pausing Foreign Corrupt Practices Act Enforcement to Further American Economic and National Security. The executive order ordered the Attorney General of the United States to (i) review in detail all existing FCPA investigations or enforcement actions, (ii) to take appropriate action to restore proper bounds on FCPA enforcement, and (iii) cease initiation of any new FCPA investigations or enforcement actions unless the Attorney General determines that an individual exception should be made. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. On June 9, 2025, the DOJ issued new FCPA enforcement guidelines, formally ending the moratorium imposed by President Trump's executive order. These new guidelines articulate DOJ's refined priorities with far greater specificity, directing prosecutors to focus on cases involving cartels and transnational criminal organizations, conduct that causes concrete harm to U.S. companies, and corruption affecting critical infrastructure or other areas tied to U.S. strategic interests. The new guidelines also make clear that DOJ intends to concentrate on what it characterizes as the most consequential forms of bribery, which include schemes involving sophisticated concealment tactics, obstruction of justice or substantial illicit payments, rather than lower-level conduct or practices resembling generally accepted business courtesies. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our future approved products and technology may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our future products and technology, or our failure to obtain any required import or export authorization for our future products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our future products may create delays in the introduction of such products in international markets or, in some cases, prevent the export of those products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our future products by, or in our decreased ability to export our future products to existing or potential customers with international operations. Any decreased use of our future products or limitation on our ability to export or sell access to our future products would likely adversely affect our business.

Risks Related to Our Class A Common Stock and the Securities Market

The price of our Class A common stock has been, and may continue to be, volatile, which could result in substantial or total losses for investors.

The trading price of our Class A common stock has been and may continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- the timing and results, or perception of the results, of preclinical studies and clinical trials of our investigational product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our or our competitors' investigational product candidates or approved products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- Class A common stock price and volume fluctuations attributable to inconsistent trading volume levels of our Class A common stock;

- announcement or expectation of additional financing efforts;
- sales of our Class A common stock by us, our insiders, or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our Class A common stock. Additionally, in the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

There may not be sufficient liquidity in the market for our securities in order for investors to sell their shares.

We are a small company that is relatively unknown to stock analysts, stockbrokers, institutional investors and others in the investment community that generate or influence sales volume, and even if we came to the attention of such persons, they tend to be risk-averse and may be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. There may be periods of several days or more when trading activity in our shares is minimal as compared to a mature issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. It is possible that a broader or more active public trading market for our Class A common stock will not develop or be sustained, or that trading levels will not continue. These factors may materially adversely affect the market price of our Class A common stock, regardless of our performance.

We will need to raise substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, scale back or discontinue some of our investigational product candidate development programs or commercialization efforts.

The development of pharmaceutical drugs is capital intensive. We are currently advancing laromestrocel into clinical development. As a result of the recently completed private placement financing referenced in Note 14, Subsequent Events, and based on current operating plans, we expect that our cash and cash equivalents as of December 31, 2025 plus proceeds from the private placement will fund operations into the fourth quarter of 2026. The Company also has access to an At-The-Market (ATM) equity financing vehicle for the sale of up to $10.7 million aggregate market value of shares of the Company's Class A common stock. We will require additional funds to advance further. If we are capital constrained, we may not be able to meet our obligations. If we are unable to meet our obligations, or we experience a disruption in our cash flows, it could limit or halt our ability to continue to develop our current investigational product candidate or even to continue operations, either of which occurrence would have a material adverse effect on us.

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current investigational product candidate. Following a successful Type C meeting with the FDA in August 2024 with respect to the HLHS regulatory pathway, we began ramping up BLA enabling activities, with a focus on clinical spend supporting HLHS study completion and delivering top-line results. The Company currently anticipates a potential BLA filing with the FDA in 2027 and plans to seek a commercialization partner if the current ELPIS II trial in HLHS is successful. Additionally, following a positive Type B meeting with the FDA in March 2025 with respect to the AD regulatory pathway, we are focused on seeking partnership opportunities and/or non-dilutive funding for the AD program, including a proposed single, pivotal seamless adaptive Phase 2/3 clinical trial. The Company expects that its current operating plan will require increased spending and additional capital investments to support these initiatives, and intends to seek additional financing through capital raises, non-dilutive funding options, and commercial partnering across all indications. There can be no assurance the Company will be able to attain future financing at terms favorable to the Company or at all. In the event the Company is unable to attain the financing needed, it will need to materially revise its current operational plan. The Company may need to adjust its current and future spending levels if needed based on the level of cash available.

In addition, if we obtain marketing approval for any of our current or future investigational product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current investigational product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to continue to incur significant costs associated with operating as a public company. If we are unable to raise capital when needed, we could be forced to delay, scale back or discontinue the development and commercialization of one or more of our investigational product candidates, delay our pursuit of potential licenses or acquisitions, or significantly reduce or cease our operations.

As a result of the recently completed private placement financing referenced in Note 14, Subsequent Events, and based on current operating plans, we expect that our cash and cash equivalents as of December 31, 2025 plus proceeds from the private placement will fund operations into the fourth quarter of 2026. In past years, we have been able to fund a large portion of our clinical programs with the use of grant funding. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future investigational product candidates;
- the potential additional expenses attributable to adjusting our development plans (including any supply-related matters) in response to global geopolitical conditions and/or future public health crises;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future investigational product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or are entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or license other current or future investigational product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our current or future investigational product candidates.

Identifying potential current or future investigational product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales.

In addition, our current or future investigational product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current or future investigational product candidates.

Disruptions in the financial markets in general have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional

securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future investigational product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly delay, scale back or discontinue one or more of our research or development programs, activities to prepare for a potential BLA filing, including CMC and manufacturing readiness, or the commercialization of any investigational product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

If we continue to fail to meet the requirements for continued listing on Nasdaq, our Class A common stock could be delisted from trading on Nasdaq, which would likely reduce the liquidity of our Class A common stock and could cause our trading price to decline.

Minimum Bid Price Requirement

Our Class A common stock is currently listed for quotation on the Nasdaq Capital Market. We are required to meet listing requirements in order to maintain our listing on Nasdaq. We could lose our listing on Nasdaq if the closing bid price of our Class A common stock does not increase or if in the future, we fail to meet any of the other Nasdaq listing requirements. The loss of our Nasdaq listing would in all likelihood make our Class A common stock significantly less liquid and adversely affect its value.

On September 22, 2025, we received a notice from the Listing Qualifications Department of Nasdaq that our Class A common stock did not meet the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement") as a result of the closing bid price of the Company's Class A common stock for the last 30 consecutive business days. The notice does not result in the immediate delisting of the Company's Class A common stock and, pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company has an initial period of 180 calendar days, or until March 23, 2026 (the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement.

If, at any time before the Compliance Date, the bid price closes at $1.00 or more per share for a minimum of ten consecutive business days (subject to Nasdaq's discretion to increase the minimum period to up to 20 consecutive business days pursuant to Nasdaq Listing Rule 5810(c)(3)(H)), Nasdaq would provide written notification to the Company that it again complies with the Minimum Bid Price Requirement and the Class A common stock will continue to be eligible for listing on The Nasdaq Capital Market unless other eligibility deficiencies exist. However, pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(iii), if the Company's Class A common stock has a closing bid price of $0.10 or less for ten consecutive trading days before the Compliance Date, Nasdaq can issue a Staff Determination Letter, which, unless appealed, would subject our Class A common stock to immediate suspension and delisting.

If the Company does not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, the Company could be eligible for an additional 180 calendar day compliance period. To qualify, the Company would be required to meet the continued listing requirements for the market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of its intention to cure the deficiency during the additional compliance period. If the company falls out of compliance with any other listing requirement, including maintaining the initial listing standard of a minimum stockholder's equity of $5 million, it may not be eligible to receive an additional 180 day calendar compliance period for the Minimum Bid Price Requirement.

In the event of a delisting from the Nasdaq Capital Market, our Class A common stock would likely be traded in the over-the-counter inter-dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as the Nasdaq

Capital Market, or Exchange-listed stocks. Many OTC stocks trade less frequently and in smaller volumes than Exchange-listed stocks. Accordingly, our Class A common stock would be less liquid than it would be otherwise. Also, the prices of OTC stocks are often more volatile than Exchange-listed stocks. Additionally, many institutional investors are prohibited from investing in OTC stocks, and it might be more challenging to raise capital when needed.

The Company intends to monitor the closing bid price of the Class A common stock and assess its available options to regain compliance with the Minimum Bid Price Requirement, if necessary, and continue listing on The Nasdaq Capital Market. There can be no assurance that the Company will be able to regain compliance with the Minimum Bid Price Requirement or will otherwise be in compliance with other applicable Nasdaq listing rules. If among such options the Company elects to pursue a reverse stock split to regain compliance with the Minimum Bid Price requirement, there can be no assurance that it would accomplish this objective for any meaningful period of time, or at all, or that it would result in any permanent or sustained increase in the market price of our Class A common stock; and if such an event would be viewed unfavorably by the market, it could have the effect of reducing our market capitalization. Furthermore, pursuant to a recent modification to Nasdaq's listing standards, if a company effects a reverse stock split and within one year thereafter becomes non-compliant with the Minimum Bid Price Requirement, it would immediately receive a notification letter from the Nasdaq Listing Qualifications Department commencing delisting proceedings, with no opportunity for a compliance period.

Audit Committee Composition

On March 4, 2026, we notified Nasdaq that, as a result of the resignation of Mr. Richard Kender as a member of the Board of Directors of the Company and as chairman of the Audit Committee and the audit committee financial expert, as described below, we are temporarily no longer in compliance with Nasdaq Listing Rule 5605(c)(2)(A), which requires that the audit committee of a listed company be composed of at least three independent directors and that at least one member qualifies as an audit committee financial expert.

Also on March 4, 2026, we appointed Dr. Roger Hajjar, an existing Board Member, as a member of the Audit Committee to satisfy Nasdaq Listing Rule 5605(c)(2)(A)'s requirement that the audit committee of a listed company be composed of at least three (3) independent members. However, because no member of the Audit Committee qualifies as an audit committee financial expert, we plan to appoint, or submit to the stockholders for election, at least one (1) director that will be deemed both "independent" and an "audit committee financial expert," as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act of 1933, as amended, and under Nasdaq Listing Rule 5605(c)(2), at the earlier of the next annual shareholders meeting or within the 180-day cure period available under Nasdaq Listing Rule 5605(c)(4).

The dual-class structure of our common stock may adversely affect the trading market for our Class A common stock.

We cannot predict whether our dual class structure will result in a lower or more volatile market price of our Class A common stock or in adverse publicity or other adverse consequences. For example, certain index providers have announced restrictions on including companies with dual class or multi-class share structures in certain of their indexes. Our dual class capital structure could make us ineligible for inclusion in certain indices and mutual funds, exchange-traded funds and other investment vehicles that attempt to passively track these indices will not be investing in our stock. These policies are still fairly new, and it is as of yet unclear what effect, if any, they will have on the valuations of publicly traded companies excluded from the indices, but it is possible that they may depress these valuations compared to those of other similar companies that are included. Furthermore, we cannot assure you that other stock indices will not take a similar approach to S&P, Dow Jones or FTSE Russell in the future. Exclusion from indices could make our Class A common stock less attractive to investors and, as a result, the market price of our Class A common stock could be adversely affected.

Holders of our Class B common stock exert considerable control over the direction of our business and their ownership of our Class B common stock can prevent other stockholders from influencing significant decisions. Holders of our Series A non-voting preferred stock also have influence over certain significant corporate decisions.

As of March 9, 2026, three holders of our Class B common stock control voting rights over approximately 27% of the combined voting power of our Class A common stock and Class B common stock. For so long as holders of Class B common stock continue to hold their current shares, they will be able to significantly influence the composition of our Board of Directors and the approval of actions requiring stockholder approval through their voting power. Accordingly, for such period of time, these holders will have significant influence with respect to our management, business plans and policies. The concentration of ownership could deprive stockholders of an opportunity to receive a premium for shares of Class A common stock as part of a sale of our Company and ultimately might affect the market price of our Class A common stock.

On March 10, 2026, we entered into a Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (each, an "Investor" and collectively, the "Investors"), pursuant to which the Company agreed to issue and sell shares of the Company's Class A common stock, par value $0.001 per share (the "Common Stock") and, shares of the Company's Series A Non-Voting Convertible Preferred Stock, par value $0.001 per share, and stated value of $1,000 per share (the "Series A Preferred Stock," and together with the Common Stock, the "Securities") to the Investors in up to two closings in a private placement (the "Private Placement").

On March 10, 2026, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock with the Secretary of State of the State of Delaware (the "Certificate of Designation") in connection with the Private Placement. The Certificate of Designation provides for the issuance of up to 26,975 authorized shares of the Company's Series A Preferred Stock.

Holders of shares of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal to, on an as-if-converted-to-Common Stock basis, and in the same form as dividends actually paid on shares of the Common Stock. Except as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock, (b) alter or amend the Certificate of Designation, (c) amend its certificate of incorporation or other governing documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (d) issue further shares of Series A Preferred Stock or increase or decrease the number of authorized shares of Series A Preferred Stock, subject to certain exceptions, or (e) consummate any Fundamental Transaction (as defined in the Certificate of Designation), certain change of control transactions or enter into any agreements with respect to the same. The Series A Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company. Issuances of securities pursuant to the Purchase Agreement, however, will not be deemed a "Fundamental Transaction."

Subject to the terms and limitations contained in the Certificate of Designation, the Series A Preferred Stock issued in the Private Placement is immediately convertible, at the option of the holder, into shares of Common Stock at a conversion price equal to the Share Price of $0.52, subject to certain limitations, including that shares of Series A Preferred Stock shall not be convertible if the conversion would result in a holder, together with its affiliates beneficially owning more than 4.99% of the Company's shares of Common Stock outstanding (or deemed to be outstanding) as of the applicable conversion date, which may be increased at the holder's option (not to exceed 9.99%), effective in accordance with the terms of the Certificate of Designation. The number of shares of Common Stock issuable upon conversion of each share of Series A Preferred Stock shall be determined by dividing the stated value of $1,000 per share by the conversion price of $0.52 (subject to adjustment as set forth in the Certificate of Designation).

If securities or industry analysts do not publish research or reports, or if they publish negative, adverse, or misleading research or reports, regarding us, our business or our market, our Class A common stock price and trading volume could decline.

The trading market for our Class A common stock is influenced by the research and reports that securities or industry analysts publish about us, our business, or our market. We do not currently have significant research coverage and may never obtain significant research coverage by securities or industry analysts. If no or few securities or industry analysts provide coverage of us, the Class A common stock price could be negatively impacted. In the event we obtain

significant, or any securities or industry analyst coverage and such coverage is negative, or adverse or misleading regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our Class A common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our Class A common stock price or trading volume to decline.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our securities.

Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that "A broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer." This is a significantly higher standard for broker-dealers to recommend securities to retail customers than before under prior FINRA suitability rules. FINRA suitability rules do still apply to institutional investors and require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information, and, for retail customers, determine that the investment is in the customer's "best interest," and meet other SEC requirements. Both SEC Regulation Best Interest and FINRA's suitability requirements may make it more difficult for broker-dealers to recommend that their customers buy speculative, low-priced securities. They may affect investing in our Class A common stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker-dealers may be willing to make a market in our Class A common stock, reducing a stockholder's ability to resell shares of our Class A common stock.

Provisions in our Certificate of Incorporation and Bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A common stock.

Our Certificate of Incorporation and Bylaws contain provisions that could depress the market price of our Class A common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified Board of Directors so that not all members of our Board are elected at one time;
- permit only the Board of Directors to establish the number of directors and fill vacancies on the Board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- provide for a dual class common stock structure, which provides certain affiliates of ours, including our co-founder and members of our Board, individually or together, with the ability to significantly influence the outcome of matters requiring stockholder approval, even if they own significantly less than a majority of the shares of our outstanding Class A common stock and Class B common stock;
- authorize the issuance of "blank check" preferred stock that our Board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our Board to amend our Bylaws;

- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our Certificate of Incorporation, Bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our Class A common stock.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Class A common stock less attractive to investors.

We are currently an emerging growth company, or EGC, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (i.e., December 31, 2026), (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our Class A common stock less attractive if we rely on certain or all of these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.

We are not restricted from issuing additional shares of our Class A common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, Class A common stock, other than as described in this 10-K. As of March 9, 2026, we had an aggregate of 84,295,000 shares of Class A common stock authorized and of that approximately 34,497,525 shares that are not issued, outstanding or reserved for issuance (for purposes of warrant exercise or under the Company's current Third Amended and Restated 2021 Incentive Award Plan, exclusive of shares that may be issued under the Company's existing ATM Agreement). We may issue all of these shares without any action or approval by our stockholders. We may expand our business through complementary or strategic business combinations or acquisitions of other companies and assets, and we may issue shares of Class A common stock in connection with those transactions. The market price of our Class A common stock could decline as a result of our issuance of a large number of shares of Class A common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our Class A common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued

in connection with these activities, the exercise of warrants or stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our Class A common stock.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

We have never commercialized an investigational product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized an approved product, and we currently have no sales force, marketing or distribution capabilities, nor do any of our current employees have any experience in commercializing a regulated product. To achieve commercial success for our investigational product candidates, if they are approved, which we may license to others, we will rely on the assistance and guidance of those collaborators. For future approved products for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our future approved products on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our future approved products and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our future approved products. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our future approved products, we may not generate revenues from them or be able to reach or sustain profitability.

We may be required to implement employee furloughs or other workforce reductions, which could adversely affect our business, financial condition, and results of operations.

The Company is currently undertaking certain cost-savings efforts, which include a reduction in Board of Directors' fees and a reduction in executive compensation, among other cost saving opportunities such as reduction in consulting fees, travel and negotiation of temporary discounts with key vendors. Such reductions became effective on or about February 16, 2026.

The implementation of furloughs or similar actions may result in decreased employee morale and productivity, increased voluntary attrition, difficulty attracting and retaining qualified personnel, and potential reputational harm. In addition, workforce reductions may disrupt our operations, delay strategic initiatives, impair our ability to meet customer demand, and result in additional restructuring charges or cash expenditures.

There can be no assurance that any such cost-reduction initiatives would be sufficient to offset declines in revenue or increases in expenses. Moreover, repeated or prolonged workforce actions could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

In order to successfully implement our plans and strategies, we will need to grow our organization, and we may experience difficulties in managing this growth.

In order to successfully implement our development and commercialization plans and strategies, and as we continue operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including preclinical and clinical studies and investigations, as well as FDA, PMDA and other comparable foreign regulatory authorities review process for any current or future investigational product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize, any current or future investigational product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our current and future investigational product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current and future investigational product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures, our computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as HIPAA, the Health Information Technology for Economic and Clinical Health Act and GDPR), it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture our investigational product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development, approval, and commercialization of our investigational product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Although our first year incurring NOLs was for the tax year ended 2021, the net operating loss carryforwards, or NOLs, could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in ownership. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

A variety of risks associated with marketing our investigational product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our investigational product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our investigational product candidates, if any. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking platform. In addition, we may encounter attacks on social media regarding our company, management, investigational product candidates or future approved products. Finally, social media may aid in the social reform of current drug prices. For example, CVS's "CostVantage" program is regularly referred to on social media and may have an impact on how pharmaceutical products are priced in the future. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

The Company's Board of Directors (the "Board") recognizes the critical importance of maintaining the trust and confidence of our customers, clients, business partners and employees. The Board is actively involved in oversight of the Company's risk management program, and cybersecurity represents an important component of the Company's overall approach to enterprise risk management ("ERM"). The Company's cybersecurity policies, standards, processes, and practices are fully integrated into the Company's ERM program and are based on recognized frameworks established by the National Institute of Standards and Technology, the International Organization for Standardization and other applicable industry standards. In general, the Company seeks to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that the Company collects and stores by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As one of the critical elements of the Company's overall ERM approach, the Company's cybersecurity program is focused on the following key areas:

- **Governance:** As discussed in more detail under the heading "Governance," The Board's oversight of cybersecurity risk management is supported by the Audit Committee of the Board (the "Audit Committee"), which regularly interacts with the Company's General Counsel ("GC"), Chief Technology Officer ("CTO"), Director of Information Technology, and other members of management and relevant management committees, including the Company's Senior Leadership Team ("SLT"), regarding cybersecurity oversight and risk management.
- **Collaborative Approach:** The Company, through its information technology partner, has implemented a comprehensive, cross-functional approach to identifying, preventing, and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.

- **Technical Safeguards:** The Company, through its information technology partner, deploys technical safeguards that are designed to protect the Company's information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti- malware functionality and access controls, which are evaluated and improved through vulnerability assessments, penetration testing, and cybersecurity threat intelligence.

- **Incident Response and Recovery Planning:** The Company, with its information technology partner, maintains comprehensive incident response and recovery plans that fully address the Company's response to a cybersecurity incident.

- **Education and Awareness:** The Company, through its information technology partner, provides regular, mandatory training for personnel regarding cybersecurity threats to equip the Company's personnel with effective tools to address cybersecurity threats, and to communicate the Company's evolving information security policies, standards, processes, and practices.

- **Third-Party Risk Management:** The Company recognizes that cybersecurity risks may arise from third-party service providers, including its information technology partners and other vendors that process, store, or have access to Company information. As part of its enterprise risk management program, the Company maintains processes designed to identify, assess, and oversee cybersecurity risks associated with third parties. These processes may include risk-based due diligence prior to engagement, contractual requirements regarding information security controls and incident notification, periodic reassessments, review of independent audit reports and certifications where available, and ongoing monitoring of vendor performance. Cybersecurity risks associated with third parties are incorporated into the Company's overall risk management and reporting structure, and material risks or incidents are escalated to senior management and the Audit Committee, as appropriate.

The Company engages in the periodic assessment and testing of the Company's policies, standards, processes, systems, and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, including audits, assessments, tabletop exercises, threat modeling, vulnerability and penetration testing and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. The Company with our information technology partner, regularly engages assessments on our cybersecurity measures, including information security maturity assessments, audits and independent reviews of our information security control environment and operating effectiveness. The results of such assessments, audits and reviews are reported to the CTO and GC who shares data with the SLT and Audit Committee, and the Company adjusts its cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews.

Governance

The CTO, in coordination with the SLT, oversees the Company's ERM process, including the management of risks arising from cybersecurity threats. The CTO and the SLT, through its information technology partner receives regular reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, the threat environment, technological trends and information security considerations. On an annual basis, the Audit Committee and the Board discuss the Company's approach to cybersecurity risk management with the members of the SLT, which includes the Company's CTO, GC, Chief Executive Officer and Chief Financial Officer ("CFO").

The CTO, in coordination with the SLT, works collaboratively across the Company to implement a program designed to protect the Company's information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents in accordance with the Company's incident response and recovery plans. To facilitate the success of the Company's cybersecurity risk management program, multidisciplinary teams are prepared to address cybersecurity threats and to respond to cybersecurity incidents. Through ongoing communications with the Company's information technology partner, these teams monitor the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real time and report such threats and incidents to the Company's SLT and Audit Committee, when appropriate.

The Company's information technology partner has worked in information technology and information security for over 30 years with over 300 employees with six locations in the United States. A virtual Chief Information Officer from the partner works directly with the Company to align business and technical strategies, decisions, and implementations. The CTO has nearly 20 years of experience in the pharmaceutical and biotech industry managing programs and projects across a variety of implementation methodologies and risk factors and holds undergraduate degrees and certifications in his respective field. The Company's Chief Executive Officer, CFO and General Counsel each hold undergraduate and graduate degrees in their respective fields, and each have over 25 years of experience managing risks at similar companies, including risks arising from cybersecurity threats.

Cybersecurity threats, including the results of any previous cybersecurity incidents, have not materially affected nor are reasonably likely to affect the Company, including its business strategy, results of operations or financial condition.

Item 2. Properties

Our principal executive offices are located at 1951 NW 7th Avenue, Suite 520, Miami, Florida 33136. We rent approximately 15,000 ft^2 of space, which includes our executive offices and cGMP manufacturing facility, and research and development operations. This property is used by the Company's single operating segment focused on developing regenerative medicines to address unmet medical needs. See "*Manufacturing*" on page 5 of this 10-K for additional details regarding our facilities.

Item 3. Legal Proceedings

From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. While management does not currently believe that the ultimate disposition of these matters will have a material adverse impact on the Company's results of operations, cash flows, or financial position, litigation is inherently unpredictable, and depending on the nature and timing of these proceedings, an unfavorable resolution could materially affect the Company's future results of operations, cash flows or financial condition in a particular period. As of December 31, 2025, the Company is not aware of any legal proceedings or material developments requiring disclosure.

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 for Common Stock; Holders

Our Class A common stock is traded on The Nasdaq Capital Market under the symbol "LGVN." Our Class B common stock is not listed or traded on any stock exchange or other market. Shares of Class A common stock are entitled to one (1) vote per share. Shares of Class B common stock are entitled to five (5) votes per share. Holders of our Class A common stock and Class B common stock generally vote together as a single class, unless otherwise required by law or our Certificate of Incorporation. Each share of our Class B common stock is convertible into one share of our Class A common stock at any time and converts automatically upon certain transfers. The Class A common stock is not convertible into Class B common stock.

Holders of Common Stock

As of March 9, 2026, there were 18 and 12 holders of record of our Class A and Class B common stock, respectively, based on information provided by our transfer agent, Colonial Stock Transfer Co., Inc. As of such date, 21,783,749 shares of our Class A common stock and 1,484,005 shares of our Class B common stock were issued and outstanding.

Dividends

We have never declared nor paid any cash dividends, and we currently intend to retain all our cash and any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities; Repurchases of Securities

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares (or Units) Purchased (a)	Average Price Paid per Share (or Unit)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number or Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
October 1-31, 2025	77,808	$ 0.75	—	—
November 1-30, 2025	—	—	—	—
December 1-31, 2025	—	—	—	—
Total	77,808	$ 0.75	—	—

(a) Includes shares withheld from employees to satisfy minimum tax withholding obligations associated with the vesting of restricted stock units during the period.

The information set forth under Part III, Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters — Equity Compensation Plan Information" is incorporated herein.

Item 6. Reserved

Reserved.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes thereto and other financial information appearing elsewhere in this 10-K. This 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. See "Cautionary Note Regarding Forward-Looking Statements" and Part I, Item 1A, "Risk Factors." Readers are also urged to carefully review and consider these and other disclosures made by us which attempt to advise interested parties of the factors which affect our business. Operating results are not necessarily indicative of results that may occur in future periods.

Introduction and Overview

We are a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. Our lead investigational product is laromestrocel.

We are currently pursuing three potential indications: Hypoplastic Left Heart Syndrome ("HLHS"), Alzheimer's disease ("AD") and pediatric Dilated Cardiomyopathy ("pediatric DCM"). Our mission is to continue to advance the development and regulatory approval of laromestrocel in order to make it available for patients who may need it.

Financial Overview

As of December 31, 2025, we have sold 20,328,220 shares of Class A common stock through our IPO and subsequent follow-on public and private equity offerings and transactions. Additionally, as of December 31, 2025, warrants exercisable for an aggregate of up to 21,920,318 shares of our Class A common stock remain outstanding at exercise prices ranging from $0.85 per share to $175.00 per share.

In the third quarter of 2025, we undertook two capital raising transactions. On August 11, 2025, we closed a public offering of 5,882,354 shares of Class A common stock and pre-funded warrants, which were sold together with Class A common warrants to purchase up to 14,705,885 shares of Class A Common Stock. The combined public offering price was $0.85 per share of Class A common stock and related Class A common stock warrants and $0.849 per pre-funded warrant and related Class A common stock warrants. The gross proceeds to the Company from the offering were approximately $5.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company. On September 19, 2025, we entered into an At The Market Offering Agreement (the "ATM Agreement") providing for the sale and issuance by the Company of shares of Class A common stock from time to time, through or to H.C. Wainwright & Co., LLC ("Wainwright") as the Company's sales agent or principal. The aggregate market value of the shares of Class A common stock eligible for sale under the ATM prospectus supplement is currently $10.7 million. See further discussion of these transactions under Capital Raising Efforts in LIQUIDITY AND CAPITAL RESOURCES section below.

On March 11, 2026, we completed an initial closing of a private placement transaction with certain institutional and accredited investors, pursuant to which an aggregate of 6,013,384 shares of common stock were sold at a purchase price of $0.52 per share and 11,873.04 shares of Series A Preferred Stock convertible into an aggregate of 22,832,770 shares of common stock were sold at a purchase price of $1,000.00 per preferred share.

Additionally, we agreed to sell to the investors an interest in 50% of proceeds received (after deducting necessary, documented third-party fees or charges) from the potential future sale of a Rare Pediatric Disease Priority Review Voucher to the extent received from the U.S. FDA in connection with the Company's laromestrocel program for Hypoplastic Left Heart Syndrome (HLHS). The aggregate gross proceeds from the initial closing were approximately $15.9 million, before deducting placement agent fees and other private placement expenses. H.C. Wainwright, who acted as the exclusive placement agent for the private placement, received a cash fee equal to 7.0% and a management fee equal to 1.0%, of the aggregate gross proceeds raised.

Subject to satisfaction or waiver of certain conditions discussed below, we also agreed to issue and sell to the investors additional shares of common stock and Series A Preferred Stock, respectively, in a second closing, for additional gross proceeds of approximately $15.0 million, before deducting placement agent fees and other private placement expenses. The second closing would occur upon satisfaction or waiver (by Investors holding at least a majority in interest of the Securities then held by the Investors, on an as-converted basis) of the closing conditions set forth under the Purchase Agreement, including (i) the Company's achievement of Phase 2b study results for

HLHS demonstrating statistical significance of the primary endpoint(s) as agreed between the Company and the U.S. FDA (the "Milestone") and (ii) achievement of a volume weighted average price per share of common stock equal to or greater than $1.85 with aggregate trading volume of at least 25,000,000 shares (in each case, subject to appropriate, proportional adjustment for any stock splits or combinations of the common stock occurring after the date of the Purchase Agreement) during any ten consecutive trading days prior to expiration of the 30 trading days following the date of the Company's first announcement via press release or a Current Report on Form 8-K of the occurrence of the Milestone.

When appropriate funding opportunities arise, we routinely apply for grant funding to support our ongoing research and since 2016 we have received approximately $16.3 million in grant awards ($11.5 million of which has been directly awarded to us and is recognized as revenue when the performance obligations are met) from the National Institute on Aging ("NIA") of the National Institutes of Health ("NIH"), the National Heart Lung and Blood Institute ("NHLBI") of the NIH, the Alzheimer's Association, and the Maryland Stem Cell Research Fund ("MSCRF") of the Maryland Technology Development Corporation, or TEDCO.

On May 12, 2025, we announced our selection as a semi-finalist team and recipient of a $250,000 Milestone 1 Award in the XPRIZE Healthspan competition from the XPRIZE Foundation, Inc., a seven-year, $101 million global competition to identify therapeutic approaches to increase human health span.

We do not yet have a product that has been approved by the FDA, and have only generated revenues from grants, The Bahamas Registry Trial and contract manufacturing. We have not yet achieved profitable operations or generated positive cash flows from operations. We have incurred recurring losses from operations since our inception, and as of December 31, 2025 we had an accumulated deficit of $132.3 million. We expect to continue to generate operating losses for the foreseeable future. As a result of the recently completed private placement financing referenced in Note 14, Subsequent Events, and based on current operating plans, the Company expects that its cash and cash equivalents as of December 31, 2025 plus the $15.9 million in gross proceeds from the private placement will fund operations into the fourth quarter of 2026. As discussed above, the Company also has access to an ATM equity financing vehicle for sale of up to $10.7 million aggregate market value of shares of the Company's Class A common stock. We expect that our current operating plan will require increased spending and additional capital investments to support these initiatives and we intend to seek additional financing through capital raises, non-dilutive funding options, and commercial partnering across all indications. There can be no assurance we will be able to attain future financing at terms favorable to us or at all. In the event we are unable to attain the financing needed, we will need to materially revise our current operational plans.

We have prepared a cash flow forecast which indicates that we do not have sufficient cash to meet our minimum expenditure commitments for one year from the date these financial statements are available to be issued and therefore we need to raise additional funds to continue as a going concern. As a result, there is substantial doubt about our ability to continue as a going concern.

Critical Accounting Estimates

We prepare our financial statements in accordance with U.S. generally accepted accounting principles, (U.S. GAAP), which requires our management to make estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis. We consider an accounting estimate to be critical if: (i) the accounting estimate involves a significant level of estimation uncertainty by requiring us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, had or are reasonably likely to have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined pursuant to Item 303(b)(3) of Regulation S-K. Our significant accounting policies and estimates are described in more detail in the accompanying Notes to the Financial Statements contained in this Annual Report on Form 10-K.

Components of Our Results of Operations

Revenue

We have generated revenue from two sources:

- **The Bahamas Registry Trial.** Participants in The Bahamas Registry Trial pay us a fee to receive laromestrocel, imported into The Bahamas, and administered at Lyford Cay Hospital, a private medical clinic in Nassau. The fee is recognized as revenue and is used to pay for the costs associated with manufacturing and testing of laromestrocel, administration, shipping and importation fees, data collection and management, biological sample collection and sample processing for biomarkers and other data, and overall management of the Registry, including personnel costs. Laromestrocel is considered an investigational treatment in The Bahamas and is not licensed for commercial sale. We refer to revenue generated from The Bahamas Registry Trial as clinical trial revenue in our statements of operations.
- **Contract development and manufacturing services.** From time to time, we enter into fee-for-service agreements with third parties for our product development and manufacturing capabilities. These agreements may include research, process development, and manufacturing services tailored to customer needs. In February 2024, we entered into our first manufacturing services contract with a third-party biotechnology company. Revenue from this contract is recognized over time as the services are provided. Additionally, the customer pays a fixed monthly fee per suite to reserve and maintain a dedicated manufacturing suite and storage space. Additional suites may also be secured based on capacity needs, which are billed at a fixed fee per suite per month. We refer to revenue generated from these services as contract manufacturing revenue in our statements of operations. During 2025, activities under the contract development and manufacturing service agreement with our customer substantially decreased. No additional manufacturing or development activities are planned and we do not anticipate significant future revenue under this agreement.

Cost of Revenues

We record cost of revenues based on expenses directly related to revenue. For the clinical trial revenue, directly related expenses for that program are allocated and accrued as incurred. These expenses are similar to those described under "Research and Development Expenses" below. For contract manufacturing revenue, directly related expenses for the services and facilities provided under the contract are recorded as cost of revenues.

Research and Development Expenses

Research and development costs are charged to expense when incurred in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730 Research and Development. ASC 730 addresses the proper accounting and reporting for research and development costs. It identifies: (1) those activities that should be identified as research and development; (2) the elements of costs that should be identified with research and development activities, and the accounting for these costs; and (3) the financial statement disclosures related to them.

Research and development expenses include costs such as clinical trial expenses, contracted research and manufacturing, license agreement fees with no alternative future use, supplies and materials, salaries, equity-based compensation, employee benefits, property and equipment depreciation and allocation of various corporate costs. We accrue for costs incurred by external service providers, including clinical investigators, based on estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, subject enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, we may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

We currently do not carry any inventory for our investigational product candidates, as we have yet to launch a product for commercial distribution. Historically our operations have focused on conducting clinical trials, product research and development efforts, and improving and refining our manufacturing processes, and accordingly, manufactured clinical doses of investigational product candidates were expensed as incurred, consistent with

the accounting for all other research and development costs. Once we begin commercial distribution, all newly manufactured approved products will be allocated either for use in commercial distribution, which will be carried as inventory and not expensed, or for research and development efforts, which will continue to be expensed as incurred.

Subject to obtaining necessary financing, we expect that our research and development expenses will continue to be significant in the future as we support increased research and development activities relating to our clinical programs, as well as incur additional expenses related to our clinical trials.

General and Administrative Expenses

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

Other Income and Expenses

We earn interest income on cash equivalents and money market funds. Other income and expense also includes items incurred that are not part of our normal operations.

Income Taxes

No provision for income taxes has been recorded for the years ended December 31, 2025 and 2024. We may incur income taxes in the future if we have earnings. At this time, we have not evaluated the impact of any future profits.

RESULTS OF OPERATIONS

COMPARISON OF THE YEARS ENDED DECEMBER 31, 2025 AND 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024, together with the changes in those items in dollars (in thousands):

	Year Ended December 31,		Increase (Decrease)
	2025	2024	
Revenues	$ 1,199	$ 2,392	$ (1,193)
Cost of revenues	396	508	(112)
Gross profit	803	1,884	(1,081)
Operating Expenses			
General and administrative	12,049	10,269	1,780
Research and development	12,041	8,137	3,904
Total operating expenses	24,090	18,406	5,684
Loss from operations	(23,287)	(16,522)	6,765
Other income and (expense)			
Loss on disposal of assets	(97)	—	97
Other income, net	680	549	131
Total other income, net	583	549	34
Net loss	$ (22,704)	$ (15,973)	$ 6,731

Revenues, Cost of Revenues and Gross Profit: Revenues for the year ended December 31, 2025 were $1.2 million and consisted of $1.0 million of clinical trial revenue and $0.2 million of contract manufacturing revenue. Revenues for the year ended December 31, 2024 were $2.4 million and consisted of $1.4 million of clinical trial revenue, $0.5 million of contract manufacturing lease revenue, and $0.5 million of contract manufacturing revenue. 2025 revenues decreased $1.2 million, or 50%, when compared to 2024, as a result of lower participant demand for our Bahamas Registry Trial and reduced demand for contract manufacturing services from our third-party client.

Related cost of revenues was $0.4 million and $0.5 million for the years ended December 31, 2025 and 2024, respectively. This resulted in a gross profit of approximately $0.8 million for the year ended December 31, 2025, a decrease of $1.1 million, or 57%, when compared with a gross profit of $1.9 million for 2024.

General and Administrative Expense: General and administrative expenses for the year ended December 31, 2025 increased to approximately $12.0 million compared to $10.3 million for the same period in 2024. The increase of approximately $1.8 million, or 17%, was primarily related to an increase in personnel and related costs in 2025 as we increased headcount year over year and accrued severance costs for our former CEO Wa'el Hashad.

Research and Development Expenses: Research and development expenses for the year ended December 31, 2025 increased to approximately $12.0 million from approximately $8.1 million for the same period in 2024. This increase of $3.9 million, or 48%, was primarily driven by a $2.2 million increase in personnel and related costs, including equity-based compensation, a $1.4 million increase in CMC costs associated with technology transfer, including non-clinical manufacturing batches that advance our readiness for future commercial production as part of our BLA-enabling efforts, and a $0.2 million increase in amortization expense related to patent costs.

Research and development expenses consisted primarily of the following items (in thousands):

	Year Ended December 31,	
	2025	2024
Clinical trial expenses-statistics, monitoring, labs, sites, etc.	$ 1,826	$ 2,031
CMC	1,746	327
Employee compensation and benefits	5,919	3,554
Equity-based compensation	660	825
Depreciation	761	735
Amortization	466	224
Travel	227	173
Other activities	436	268
Total	$ 12,041	$ 8,137

Other Income: Other income for the year ended December 31, 2025 was $0.6 million, consisting of $0.4 million of interest earned on money market funds and $0.3 million of cash received as a recipient of a Milestone 1 Award in the XPRIZE Healthspan competition, partially offset by a $0.1 million loss on the disposal of assets. Other income for the year ended December 31, 2024 was $0.5 million, consisting primarily of interest earned on money market funds and marketable securities.

Net Loss: Net loss increased to approximately $22.7 million for the year ended December 31, 2025 from a net loss of $16.0 million for the same period in 2024. The increase in the net loss of $6.7 million, or 41%, was for reasons outlined above.

Cash Flows

The following table summarizes our sources and uses of cash for the period presented for the (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (18,645)	$ (13,868)
Net cash used in investing activities	(595)	(640)
Net cash provided by financing activities	4,669	28,791
Net (decrease) increase in cash and cash equivalents	$ (14,571)	$ 14,283

Operating Activities. We have incurred losses since inception. Net cash used in operating activities for the year ended December 31, 2025 was $18.6 million, consisting primarily of our net loss of $22.7 million and the amortization of prepaid expenses and other current assets of $0.4 million and in operating lease asset and liability of $0.3 million. This was partially offset by non-cash expenses of $1.7 million in equity-based compensation and $1.2 million in depreciation and amortization, including intangibles. Net cash used in operating activities for the

year ended December 31, 2024 was $13.9 million, consisting primarily of our net loss of $16.0 million and payments towards accounts payable of $0.5 million and a decrease in deferred revenue of $0.5 million. This was partially offset by non-cash expenses of $2.3 million in equity-based compensation expenses and $1.0 million in depreciation and amortization.

Investing Activities. Net cash used in investing activities for the year ended December 31, 2025 was approximately $0.6 million consisting primarily of additions to intangible assets of $0.3 million and purchases of equipment of $0.2 million. Net cash used in investing activities for year ended December 31, 2024 was $0.6 million consisting primarily of additions to intangible assets of $0.3 million and purchases of equipment of $0.6 million, which was partially offset by proceeds from the sale of marketable securities of $0.3 million.

Financing Activities. Net cash provided by financing activities for the year ended December 31, 2025 was $4.7 million and primarily consists of proceeds from the issuance of common stock of approximately $5.0 million, which was partially offset by the payment of taxes upon vesting of restricted stock units ("RSUs"). Net cash provided by financing activities for the year ended December 31, 2024 was $28.8 million consisting primarily of proceeds from the issuance of common stock of $12.9 million and warrants exercised of $16.2 million, which was partially offset by the payment of taxes upon vesting of RSUs.

LIQUIDITY, CAPITAL RESOURCES, AND GOING CONCERN

We have incurred recurring losses and negative cash flows from operations since inception. We expect to incur significant expenses and operating losses as we advance the preclinical and clinical development of our programs. We expect that our sales, research and development and general and administrative costs will remain substantial in connection with conducting additional preclinical studies and clinical trials for our current and future programs and investigational product candidates, contracting with CROs to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

To date, we have financed our operations primarily through our IPO, registered and private placement equity financings, grant awards, fees generated from The Bahamas Registry Trial and contract manufacturing services. Since we were formed, we have raised approximately $119.0 million in gross proceeds from the issuance of equity, including $15.9 million in gross proceeds from the March 2026 private placement. As of December 31, 2025, we had cash and cash equivalents of $4.7 million and working capital of $1.4 million. We currently anticipate our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2026, based on our current operating budget and cash flow forecast. Our operating costs will continue to be substantial for the foreseeable future in connection with our ongoing activities. In past years we have been able to fund a large portion of our clinical programs with the use of grant funding.

Specifically, we will incur expenses to:

- advance the clinical development of laromestrocel for the treatment of several disease states and indications;
- pursue the preclinical and clinical development of other current and future research programs and investigational product candidates;
- in-license or acquire the rights to other products, investigational product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel in research, manufacturing and regulatory and clinical development as well as management personnel;
- seek regulatory approval for any investigational product candidates that successfully complete clinical development, including a potential BLA filing with the FDA in 2027 for HLHS if the current ELPIS II trial is successful, subject to sufficient resources;
- advance CMC activities to support BLA readiness; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our operations as a public company.

We intend to seek additional financing opportunities, capital raises, as well as non-dilutive funding options to support our operating plans. Additionally, following a positive Type B meeting with the FDA in March 2025 with respect to the AD regulatory pathway, we are focused on seeking partnership opportunities and/or non-dilutive funding for the AD program, including a proposed single, pivotal seamless adaptive Phase 2/3 clinical trial. There can be no assurance we will be able to attain future financing at terms favorable to us or at all. In the event we are unable to attain the financing needed, we will need to materially revise our current operational plan. We do not have sufficient cash to meet our minimum expenditure commitments for one year from the date these financial statements are available to be issued and therefore we need to raise additional funds to continue as a going concern. As a result, there is substantial doubt about our ability to continue as a going concern.

Capital Raising Efforts

As of December 31, 2025, we have sold 20,328,220 shares of Class A common stock through our IPO and subsequent follow-on public and private equity offerings and transactions. Additionally, as of December 31, 2025, warrants exercisable for an aggregate of up to 21,920,318 shares of our Class A common stock remain outstanding at exercise prices ranging from $0.85 per share to $175.00 per share.

In the third quarter of 2025, we undertook two capital raising transactions. On August 11, 2025, we closed a public offering of 5,882,354 shares of Class A common stock and pre-funded warrants, which were sold together with Class A common warrants to purchase up to 14,705,885 shares of Class A Common Stock. The combined public offering price was $0.85 per share of Class A common stock and related Class A common stock warrants and $0.849 per pre-funded warrant and related Class A common stock warrants. The gross proceeds to the Company from the offering were approximately $5.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company. The Class A common stock warrants were immediately exercisable, expire twenty-four (24) months from the date of issuance and have an exercise price equal to $0.85 per share of Class A common stock. As compensation to the placement agent, we paid a cash fee equal to 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the aggregate gross proceeds raised and certain expenses incurred. We also issued them warrants to purchase up to 411,765 shares of Class A common stock, which had substantially the same terms as the Class A common stock warrants, except that the exercise price was $1.0625 per share (which represented 125% of the combined public offering price per share and related Class A Common Stock warrants).

On September 19, 2025, we entered into an ATM Agreement providing for the sale and issuance by the Company of shares of Class A common stock from time to time, through or to Wainwright as the Company's sales agent or principal. The aggregate market value of the shares of Class A common stock eligible for sale under the ATM prospectus supplement is currently $10.7 million. Pursuant to the ATM Agreement, Wainwright has agreed to use its commercially reasonable efforts to sell the shares of Class A common stock from time to time. The Company will designate the parameters for the sale of shares of Class A common stock, including the number of shares to be issued, the time period during which sales are requested to be made, limitations on the number of shares that may be sold on any trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the ATM Agreement, Wainwright may sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including without limitation, sales made directly on Nasdaq or on any other existing trading market for the Class A common stock or to or through a market maker. In addition, with the Company's prior written approval, Wainwright may also sell shares in privately negotiated transactions or block transactions. The gross sales price of the shares of Class A common stock sold by Wainwright under the ATM Agreement as sales agent shall be the market price for the shares of Class A common stock on Nasdaq at the time of sale.

The Company has no obligation to sell any shares of Class A common stock under the ATM Agreement and the Company or Wainwright may at any time suspend offers under the ATM Agreement, pursuant to the terms therein. Wainwright is not obligated to purchase any shares of Class A common stock on a principal basis pursuant to the ATM Agreement, except as otherwise specifically agreed by Wainwright and the Company in a separate agreement. No assurance can be given that the Company will sell any shares of Class A common stock under the ATM Agreement, or if such sales occur, no assurance can be given as to the price or number of shares that will be sold, or the dates on which any such sales will take place.

The ATM Agreement provides that the Company will pay Wainwright a sales commission equal to 3.0% of the gross sales price of the shares of Class A common stock sold by Wainwright pursuant to the ATM Agreement, and provide reimbursement for reasonable fees and expenses incurred by its legal counsel in connection with the ATM Agreement. As of December 31, 2025, we have sold 1,759,626 shares of Class A common stock under the ATM Agreement at a weighted average share price of $0.67 per share, resulting in net proceeds of approximately $0.9 million to the Company after deducting certain offering expenses, including approximately $50,000 in compensation to Wainwright.

The ATM Offering will terminate upon the earlier of (i) the sale of the Company's Class A common stock pursuant to the ATM Prospectus Supplement having an aggregate sales price of $10.7 million or (ii) termination of the ATM Agreement by the Company or Wainwright as permitted therein.

See Note 14, Subsequent Events, for a discussion of the March 2026 private placement financing.

Grant Awards

Since 2016 through December 31, 2025, we have been directly awarded approximately $11.5 million in governmental and non-profit association grants, which have been used to fund our clinical trials, research and development, production and overhead. Grant awards are recognized as revenue, and depending on the funding mechanism, are deposited directly in our accounts as lump sums, which are staggered over a predetermined period or drawn down from a federal payment management system account for reimbursement of expenses incurred. Revenue recognition occurs when the grant related expenses are incurred or supplies and materials are received. Grant revenues were $0 in both 2025 and 2024. As of December 31, 2025, and 2024, the amount of unused grant funds that were available for us to draw was approximately $0 and $0.1 million, respectively.

The following table summarizes the grants awarded.

Longeveron Project	Funding Agency[1]	Total Amount ($)	Status of Award
Aging-related frailty Phase 2b Trial	SBIR (DHHS) NIA	3,957,813	Complete
Aging-related frailty Phase 2b Trial	SBIR (DHHS) NIA	283,040	Complete
Alzheimer's Disease Phase 1 Trial[2]	Alzheimer's Association	3,000,000	Complete
Alzheimer's Disease Phase 1 Trial	Alzheimer's Association	1,000,000	Complete
The Metabolic Syndrome Sub-Study	STTR (DHHS) NIA	150,000	Complete
The Metabolic Syndrome Sub-Study	STTR (DHHS) NIA	901,486	Complete
Aging-related frailty Influenza Vaccine Trial ("HERA")	MSCRF – TEDCO	750,000	Complete
HLHS Phase 1 Trial	MSCRF – TEDCO	750,000	Complete
HLHS Phase 2 Trial[3]	UG3 (DHHS) NHLBI	477,566	Complete
ARDS Phase 1.	MSCRF – TEDCO	650,000	Complete
Total		**11,919,905**	

(1) SBIR=Small Business Innovation Research programs; STTR=Small Business Technology Transfer programs; DHHS=Department of Health and Human Services; NIA = National Institute on Aging; NHLBI=National Heart, Lung, and Blood Institute.

(2) Under the grant award agreement with the Alzheimer's Association, we may be required to make revenue sharing or distribution of revenue payments for products or inventions generated or resulting from this clinical trial program. The potential payments, although not currently defined, could result in a maximum payment of five times (5x) the award amount.

(3) The HLHS Phase 2b clinical trial grant was awarded to Sunjay Kaushal, M.D., Ph.D, Ann and Robert H. Lurie Children's Hospital of Chicago, and the trial will be conducted under our IND and will test laromestrocel. The total award was $4.2 million, and we have received $0.3 million of the approximately $0.5 million apportioned to us.

Terms and Conditions of Grant Awards

Governmental grant projects are typically divided into periods (e.g., a three-year grant may have three one-year periods), and the total amount awarded is divided according to the number of periods. At pre-specified time points, which are detailed in the grant award notifications, we are required to submit interim financial and scientific reports to the granting agency totaling funds spent, and in some cases, detailing use of proceeds and progress made during the reporting period. After funding the initial period, receipt of additional grant funds is contingent upon satisfactory submission of our interim reports to the granting agency.

In addition to governmental grants, the Company also receives awards from non-profit foundations through competitive application processes, where funding is typically distributed in stages as specific milestones are met.

Grant awards arise from submitting detailed research proposals to granting agencies and other organizations and winning a highly competitive and rigorous application review and process that is judged on the merits of the proposal. There are typically multiple applicants applying and competing for a finite amount of funds. As such we cannot be sure that we will be awarded grant funds in the future despite our past success in receiving such awards.

Funding Requirements

Because of the numerous risks and uncertainties associated with research, development and commercialization of our investigational product candidates, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs and results of our clinical trials for our programs for our cell-based therapies, and additional research and preclinical studies in other research programs we initiate in the future;
- the costs and timing of process development and manufacturing scale-up activities associated with our investigational product candidates and other programs we advance through preclinical and clinical development;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the extent to which we in-license or acquire rights to other products, investigational product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

Further, our operating results may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans. Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, grant awards, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements and marketing and distribution arrangements.

We currently have no credit facility or committed sources of capital. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or investigational product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our biologic drug development or future commercialization efforts or grant rights to develop and market products or investigational product candidates that we would otherwise prefer to develop and market ourselves.

In order to meet our operational goals, we will need to obtain additional capital, which we will likely obtain through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of convertible debt or equity securities, current stockholder ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect stockholder rights. Such financing will likely result in dilution to stockholders, and may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our investigational product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Contractual Obligations and Commitments

As of December 31, 2025, we have $0.8 million in operating lease obligations and no CRO payment obligations. From time to time we may enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

We have not included milestone or royalty payments or other contractual payment obligations if the timing and amount of such obligations are unknown or uncertain.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, which is a law intended to encourage funding of small businesses in the U.S. by easing many of the country's securities regulations, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards; and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (2) the last day of the fiscal year following the fifth anniversary of the completion of our IPO (i.e. December 31, 2026), (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which generally is when a company has more than $700 million in market value of its reported class of stock held by non-affiliates and has been a public company for at least 12 months and have filed at least one Annual Report on Form 10-K.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our audited financial statements included in Item 8 of this 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of approximately $4.7 million as of December 31, 2025. We generally hold our cash in interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained in the audited financial statements and accompanying notes located at the end of this 10-K and is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15 (e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the fiscal quarter ended December 31, 2025. Disclosure controls and procedures include, without limitation, controls and other procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC as well as accumulated and communicated to its management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management did not identify material weaknesses in our internal control over financial reporting, which is an integral component of our disclosure controls and procedures. 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 or interim financial statements will not be prevented or detected on a timely basis.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Responsibility for Financial Statements

Our management is responsible for the integrity and objectivity of all information presented in this 10-K. The financial statements were prepared in conformity with accounting principles generally accepted in the United States of America and include amounts based on management's best estimates and judgments. Management believes the financial statements fairly reflect the form and substance of transactions and that the financial statements fairly represent the Company's financial position and results of operations for the periods and as of the dates stated therein.

The Audit Committee of the Board of Directors, which is composed solely of independent directors, meets regularly with our independent registered public accounting firm, CBIZ CPAs P.C. and representatives of management to review accounting, financial reporting, internal control, and audit matters, as well as the nature and extent of the audit effort. The Audit Committee is responsible for the engagement of the independent auditors. The independent auditors have free access to the Audit Committee.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control over financial reporting required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act that occurred during the fiscal quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Our management, including the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. Management based this assessment on criteria for effective internal control over financial reporting described in "Internal Control-Integrated Framework 2013" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management determined that, as of December 31, 2025, we maintained effective internal control over financial reporting.

Item 9B. Other Information

Information Required to be Disclosed on Form 8-K for the Fiscal Quarter Ended December 31, 2025, But Not Reported

None.

Trading Arrangements

None of the Company's directors or "officers," as defined in Rule 16a-1(f) of the Exchange Act, adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K, during the Company's fiscal quarter ended December 31, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of March 9, 2026:

Name	Age	Position
Executive Officers		
Stephen H. Willard	65	Chief Executive Officer
Joshua M. Hare, M.D.	63	Co-Founder, Chief Science Officer, Executive Chairman and Director
Lisa A. Locklear	65	Chief Financial Officer and Treasurer
Paul Lehr, J.D.	58	General Counsel and Secretary
Nataliya Agafonova	56	Chief Medical Officer
Devin Blass	40	Chief Technology Officer and Senior Vice President of Chemistry, Manufacturing, and Controls
Non-Employee Directors		
George Paletta, Jr., M.D.	63	Director
Roger Hajjar, M.D.	61	Director
Rock Soffer	43	Director
Ursula Ungaro, J.D.	75	Director

Executive Officers

Stephen H. Willard. (Chief Executive Officer) was appointed in February 2026 as the CEO of Longeveron and has over 30 years of pharmaceutical and biotech leadership experience across public and private sectors, including more than 20 years of experience as the Chief Executive Officer of pharmaceutical and biotech companies, most recently at ICaPath, Inc. a biotechnology company developing novel immunotherapies in the cancer space. Prior to that time, Mr. Willard served as Chief Executive Officer of NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharma company developing therapeutics for the treatment of central nervous system disorders, from July 2022 to October 2024, and Cellphire, Inc., a clinical stage cellular therapeutics company, from November 2013 until March 2021. In addition, since March 2021 he has served as the Executive Director of Global Life Technologies (Nozin) an infection prevention company, and from March 2018 until November 2024, Mr. Willard served as a Presidentially-commissioned member of the National Science Board, which governs the National Science Foundation. Mr. Willard received a B.A. from Williams College in 1982 and a J.D. from Yale Law School in 1985, where he edited the Yale Law Journal.

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A. (Co-Founder, Chief Science Officer and Executive Chairman) co-founded Longeveron in 2014 and has served on its Board of Directors and as its Chief Science Officer since that time. In September 2025, Dr. Hare was appointed as Executive Chairman of the Board of Directors. Longeveron obtained an exclusive license to cell production technologies developed by Dr. Hare at UM. Dr. Hare is a double-boarded cardiologist (Cardiology and Advanced Heart Failure and Transplantation) and is the founding director of the Interdisciplinary Stem Cell Institute at the UM Miller School of Medicine. He has obtained in excess of $25 million in funding from the National Institutes of Health over the past 15 years to support basic research of cell therapy strategies. He is also a recipient of the Paul Beeson Physician Faculty Scholar in Aging Research Award and is an elected member of the American Association of Physicians, The American Society for Clinical Investigation, an elected Fellow of the American Heart Association, and an elected member of the National Academy of Inventors. Dr. Hare has also served in numerous leadership roles at the American Heart Association, the Heart Failure Society of America, and at the Center for Scientific Review of the National Institutes of Health. Dr. Hare is also a co-founder of Vestion, Inc., and Heart Genomics, LLC, companies that hold cardio-related intellectual property. He received a B.A. from the University of Pennsylvania, his M.D. from The Johns Hopkins University School of Medicine, and completed fellowships at Johns Hopkins and Brigham and Women's Hospital, and was a Research Fellow at Harvard Medical School.

Lisa A. Locklear, C.P.A. (inactive), M.B.A. (Chief Financial Officer ("CFO")) joined Longeveron as CFO on July 31, 2023. Prior to her time at Longeveron, Ms. Locklear served as Senior Vice President and CFO of Avanir Pharmaceuticals, a subsidiary of Otsuka, from 2018 to 2022. During her time at Avanir, Ms. Locklear was instrumental in enhancing the financial and technology-related processes, systems, and people during a period of rapid growth. Prior to Avanir, she held senior financial roles at GSN Games, CoreLogic, Ingram Micro, the Walt Disney Company and Price Waterhouse (now PwC), with assignments in Paris and London. Ms. Locklear has been recognized by the Healthcare Businesswoman's Association with the Luminary Award, an honor that underscores her dedication to fostering growth of other women's careers and her unwavering commitment to the healthcare industry. In addition to her professional career, Ms. Locklear currently chairs the Board of Governors of the Gemological Institute of America and recently served on the boards of the Pacific Marine Mammal Center and the Orange County United Way and is a member of the National Association of Corporate Directors. She holds a Bachelor of Science degree in plant science from the University of California, Davis, and an M.B.A. from the University of California, Irvine. She is a licensed Certified Public Accountant (inactive) and is a member of the American Institute of Certified Public Accountants, the California Society of CPAs, and Financial Executives International.

Paul Lehr, J.D. (General Counsel and Secretary) joined Longeveron in 2016 and serves as General Counsel and Corporate Secretary. Over the past 20 years, Mr. Lehr has held senior legal and executive positions in corporate, non-profit, and research settings. Mr. Lehr has also been the CEO of GroundUP Music Foundation, which organizes an annual music festival, since 2015. Mr. Lehr has also served since 2011 as CEO and co-founder of HeartGenomics, a biotech firm based on intellectual property Mr. Lehr licensed from the UM Miller School of Medicine. Mr. Lehr served as a law clerk for a United States Federal Judge and practiced law with experience in healthcare, business transactions and litigation at a leading Miami law firm for 5 years. Thereafter, Mr. Lehr focused his efforts in the cardiac rehabilitation field as President of a non-profit research foundation. With this research serving as the foundation of the for-profit arm of the cardiac rehabilitation program, Mr. Lehr negotiated a master franchise agreement with a leading Indian healthcare operator with 100+ facilities across India and the Middle East, then co-lead negotiations with the Centers for Medicare & Medicaid Services to successfully secure reimbursement of their residential intensive cardiac rehabilitation program. Mr. Lehr has held senior legal and executive positions in corporate as well as educational and not-for-profit settings. He earned his B.A. from Brown University, and his J.D. with honors from University of Florida College of Law.

Nataliya Agafonova, M.D. (Chief Medical Officer ("CMO")) joined Longeveron in the role of CMO on July 1, 2023. Before Longeveron, Dr. Agafonova served as Clinical Development Lead, Senior Medical Director, and Product Development Chair at Otsuka Pharmaceuticals from 2021 to 2023. Previously, she was the Clinical Development Lead and Senior Medical Director at Bristol-Myers Squibb. Dr. Agafonova previously held several senior leadership positions in clinical development and pharmacovigilance at Ardea Bioscience, Biogen, Amgen and Genzyme Corporation. She has extensive experience in therapeutic areas such as autoimmune, hematology, neuroscience, and oncology. Her cross-therapeutic expertise in drug development helped to bring several products to the U.S. and EU markets. Prior to her industry experience, Dr. Agafonova served as a physician at the Ukrainian Research Institute of Oncology and Radiology. She earned her M.D. from the Ukrainian National Medical University and completed her internal medicine residency at Kharkov State University Hospital in Ukraine.

Devin Blass (Chief Technology Officer and Senior Vice President of Chemistry, Manufacturing, and Controls) joined Longeveron on December 2, 2024 with over 15 years of experience in the development and manufacture of advanced therapies. Prior to his time at Longeveron, Mr. Blass served as the Senior Vice President of Comprehensive Cell Solutions, the contract development and manufacturing organization (CDMO) of New York Blood Center Enterprises (NYBCe), from November 2023 to December 2024. There, he oversaw the CDMO business unit, encompassing Technical Operations, Business Development, and Cell Sourcing. From November 2019 to October 2023, Mr. Blass held various roles at Talaris Therapeutics, where he ultimately served as the Vice President of Technical Operations and Site Head, managing the company's technical operations and supply chain. His career also includes directing cell manufacturing operations at Bellicum Pharmaceuticals and serving as the Director of Commercial Program Manufacturing at Mesoblast. Mr. Blass's industry experience is complemented by his significant contributions at MD Anderson Cancer Center, where he advanced through roles of increasing responsibility. There, he played a pivotal role in developing the infrastructure and systems necessary to obtain licensure for HPC and Cord Blood. Mr. Blass holds a B.S. in Biochemistry from Texas State University.

Non-Employee Directors

George Paletta, Jr., M.D., M.B.A. was appointed to the Longeveron Board of Directors in October 2025. Dr. Paletta holds multiple patents, in both orthopedic and rehabilitation arenas. He led the founding and development of Preston Worldwide, a medical device company built around the sling and pillow technology. He has been a frequent early phase investor in multiple start-up ventures across a wide range of industries and technologies, serving in both formal and informal advisory roles. Dr. Paletta received his B.A. in Chemistry from the College of Holy Cross and his M.D. from the Johns Hopkins University School of Medicine. His orthopedic residency was completed at the world-renowned Hospital for Special Surgery in New York City. His training included three post-graduate fellowships at Hospital for Special Surgery, The Cleveland Clinic and Children's Hospital of Michigan. His professional career has included both academic and private practice at Hospital for Special Surgery, Washington University School of Medicine Department of Orthopedic Surgery and, most recently, The Orthopedic Center of St. Louis. From 1998 to 2014 and from December 2016 to October 2025, Dr. Paletta served as the Head Team Orthopedic Surgeon for Major League Baseball's St. Louis Cardinals. He completed his M.B.A. from the Olin School of Business at Washington University in St Louis.

Roger Hajjar, M.D. was elected to the Longeveron Board of Directors in July 2024. Dr. Hajjar is an internationally recognized scientist whose cardiac gene therapy discoveries have spurred clinical trials for heart failure, and whose methodologies for cardiac-directed gene transfer are currently utilized by investigators around the world. He was recently head of R&D at Ring Therapeutics and was appointed as the inaugural director of the Gene and Cell Therapy Institute at Mass General Brigham. Dr. Hajjar also currently serves on the Board of Atamyo Therapeutics and of Medera. He has initiated multiple clinical trials in gene therapy for a variety of cardiovascular diseases, authored over 500 publications, and received numerous awards for his achievements in the field of cardiac gene therapy. Dr. Hajjar is a co-founder of several biotechnology companies and, from 2019 to 2022, was involved in the creation of multiple gene therapy companies at Flagship Pioneering, Cambridge, Massachusetts. Dr. Hajjar earned his B.S. in Biomedical Engineering from Johns Hopkins University and his M.D. from Harvard Medical School.

Rock Soffer was elected to Longeveron's Board of Directors in March 2020. Mr. Soffer is President, Special Project Division at Turnberry Associates, where he oversees leasing, asset acquisitions, zoning and site approvals, as well as the development of other specialty projects. He has experience in managing and securing financing for complex projects, as well as overseeing a number of developments in Florida, such as the redevelopment of an almost 200,000 square-foot open-air lifestyle shopping center in Aventura. In addition, Mr. Rock Soffer was tasked with overseeing the referendum for the new 800-key Miami Beach Convention Center luxury hotel. Upon completion, the privately funded property will be the cornerstone of the Convention Center District in Miami Beach. Mr. Rock Soffer is an advocate for responsible, environmentally sustainable development.

Ursula Ungaro, J.D. has served on Longeveron's Board of Directors since June 2021. She retired as a partner from Boies Schiller Flexner LLP on August 31, 2025 and joined JAMs through which she currently mediates and arbitrates commercial disputes. Prior to joining Boies Schiller, Ms. Ungaro served 29 years as a federal judge. Ms. Ungaro was appointed to serve on the federal U.S. District Court for the Southern District of Florida in 1992, having been nominated by President George H.W. Bush and confirmed by the U.S. Senate. In her time on the federal bench, she presided over and ruled in numerous major civil and criminal cases in legal domains ranging from constitutional principles, equal rights, securities issues, and the use of non-embryonic stem cell therapies, amongst many others. Following her graduation with honors from the University of Florida School of Law in 1975, Ms. Ungaro practiced law in Miami, Florida where in 1981 she became a partner in Tew, Critchlow, Sonberg, Traum & Friedbauer, P.A. (later merged into Finley, Kumble, Wagner, Heine, Underberg, Manley, Myerson & Casey, a national law firm). She subsequently joined Sparber, Shevin, Shapo & Heilbronner, a prestigious local law firm. She practiced law mainly in the area of complex commercial litigation, including in the areas of securities, corporate and tax law. From 1987 to 1992, Ms. Ungaro served as a trial judge on the Eleventh Judicial Circuit of the State of Florida. She has authored published articles in the areas of administrative law, legal ethics, and civil procedure. She is the recipient of several awards and has been recognized on several occasions by other organizations for her achievements in the law and service to the community. Ms. Ungaro serves on the Board of Directors of Bradford Holdings, Inc., a private holding company and on the Board of Directors of RVR, Inc., a privately held company and on the Board of the Miami-Dade Family Learning Partnership, a non-profit.

There are no family relationships among our current directors or executive officers.

Board Composition and Election of Directors

Our Board currently consists of five (5) members and we currently have four (4) vacancies. Our directors will be elected by the vote of holders of our Class A common stock and Class B common stock, voting together as a single class, with holders of our Class B common stock having five (5) votes per share. Under our Bylaws, the number of directors on our Board will be determined from time to time by our Board.

Classified Board of Directors

In accordance with our Certificate of Incorporation and Bylaws, our Board is divided into three classes with staggered, three-year terms. As of March 9, 2026, there are no directors currently serving as Class II directors. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- the Class III directors are Joshua M. Hare, Ursula Ungaro, and Roger Hajjar and their terms will expire at the annual meeting of stockholders to occur in 2027; and
- the Class I directors are George Paletta and Rock Soffer, and their terms will expire at our annual meeting of stockholders to occur in 2028.

Our Certificate of Incorporation and Bylaws provide that the authorized number of directors may be changed only by resolution of the Board. Any additional directorships resulting from an increase in the number of directors or the filling of vacancies will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock entitled to vote in the election of directors.

CORPORATE GOVERNANCE

Board of Directors and Committees of the Board

Our Board, elected by stockholders, is the ultimate decision-making body of the Company, except with respect to those matters reserved to the stockholders. The Board acts as an advisor and counselor to executive management and oversees and monitors its performance.

Our Board held eleven (11) meetings during 2025. Each director attended either in person or via teleconference at least 75% of the aggregate of all Board and applicable committee meetings during fiscal 2025 for the period in which they served as director. Although we do not have a formal policy regarding attendance by members of the Board at our annual meeting of stockholders, directors are encouraged to attend our annual meetings. One member of our current Board and three former board members were in attendance at our 2025 Annual Meeting of Stockholders, which was held virtually.

Our Board has established a standing Audit Committee; Compensation Committee; and Nominating and Corporate Governance Committee. The Company has also established a Science and Strategy Committee. Each of these committees has adopted a written charter.

Audit Committee. Our Audit Committee is comprised of three members: Dr. Paletta (chair), Ms. Ungaro and Dr. Hajjar. The Board has determined that all of the members of the Audit Committee are independent within the meaning of the Nasdaq Stock Market listing standards as well as within the meaning of Rule 10A-3 of the Exchange Act, and that each Audit Committee member is able to read and understand fundamental financial statements. The Audit Committee's responsibilities include appointing, approving the compensation of, and assessing the independence of our registered public accounting firm; overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm; reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures; coordinating our Board's oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics; discussing our risk management policies; meeting

independently with our internal auditing staff, if any, registered public accounting firm, and management; reviewing and approving or ratifying any related person transactions; and preparing the audit committee report required by SEC rules. The Board has adopted and approved a written charter for the Audit Committee. A current copy of this charter is posted on our website at *http://www.longeveron.com* under the Investor Relations section. The Audit Committee held six (6) meetings during 2025.

Currently, no member of the Audit Committee qualifies as an audit committee financial expert. However, we plan to appoint, or submit to the stockholders for election, at least one (1) director that will be deemed both "independent" and an "audit committee financial expert," as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act of 1933, as amended, and under Nasdaq Listing Rule 5605(c)(2), at the earlier of the next annual shareholders meeting or within the 180-day cure period available under Nasdaq Listing Rule 5605(c)(4).

Compensation Committee. The Compensation Committee is comprised of two members: Ms. Ungaro (chair) and Dr. Hajjar. The Board has determined that all the members of the Compensation Committee are independent within the meaning of the Nasdaq Stock Market listing standards and applicable SEC regulations and are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act. The Compensation Committee's responsibilities include reviewing and approving, or recommending for approval by the Board, the compensation of our CEO and our other executive officers; overseeing and administering our cash and equity incentive plans; reviewing and making recommendations to our Board with respect to director compensation; reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and preparing the annual compensation committee report required by SEC rules, to the extent required. The Board has adopted and approved a written charter for the Compensation Committee. A current copy of this charter is posted on our website at *http://www.longeveron.com* under the Investor Relations section.

The Compensation Committee may form and delegate authority to one or more subcommittees as it deems appropriate from time to time under the circumstances. To the extent permitted by and consistent with applicable law and the provisions of a given equity-based plan, the Compensation Committee may delegate to one or more executive officers of the Company the power to grant options or other stock or equity-based awards pursuant to such equity-based plan to employees of the Company or any subsidiary of the Company who are not officers or directors of the Company.

The Compensation Committee's primary objectives in structuring and administering our executive officer compensation program are to attract, motivate and retain talented and dedicated executive officers; tie annual and long-term cash and stock incentives to achievement of measurable corporate and individual performance objectives; and reinforce business strategies and objectives to enhance stockholder value. To achieve these goals, our Compensation Committee maintains compensation plans that tie a portion of executives' overall compensation to key strategic goals such as the Company's financial and operational performance, as measured by metrics such as total revenue and non-GAAP operating expense. Our Compensation Committee evaluates individual executive performance along with our CEO (other than with respect to his own performance) as part of the review process.

Our Compensation Committee periodically reviews our executive officers' compensation to determine whether we provide adequate incentives and motivation to our executive officers and whether we adequately compensate our executive officers relative to comparable officers in other similarly situated companies. The Committee engaged Compensation Advisory Partners, a third-party compensation consulting firm, to advise the Compensation Committee with respect to executive compensation benchmarking and compensation and equity program structure in 2025. Management plays a significant role in the compensation-setting process for executive officers, other than the CEO, by evaluating employee performance, recommending business performance targets and establishing objectives, and recommending salary levels, bonuses and equity-based awards. The Compensation Committee held seven (7) meetings during 2025.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee is comprised of three members: Dr. Hajjar (chair), Ms. Ungaro and Dr. Paletta. The Board has determined that all the members of the Nominating and Corporate Governance Committee are independent within the meaning of the Nasdaq Stock Market listing standards and applicable SEC regulations. The Nominating and Corporate Governance Committee's responsibilities include identifying individuals qualified to become Board members; recommending to our Board the persons to be nominated for election as directors and to each Board committee; developing and recommending to our Board corporate governance guidelines, and reviewing and recommending to our Board

proposed changes to our corporate governance guidelines from time to time; and overseeing a periodic evaluation of our Board. The Board has adopted and approved a written charter for the Nominating and Corporate Governance Committee. A current copy of this charter is posted on our website at *http://www.longeveron.com* under the Investor Relations section. The Nominating and Corporate Governance Committee held four (4) meetings during 2025.

When considering a potential candidate for membership on our Board, our Nominating and Corporate Governance Committee considers relevant business and industry experience and demonstrated character and judgment. The Nominating and Corporate Governance Committee considers diversity in identifying candidates by generally seeking to achieve a diversity of occupational and personal backgrounds on the Board. However, the Nominating and Corporate Governance Committee has no formal policy regarding diversity. The Nominating and Corporate Governance Committee will consider stockholder nominations for directors submitted in accordance with the procedure set forth in Article II, Sections 2.5 and 2.6 of our Bylaws. The procedure provides that a notice relating to the nomination must be timely given in writing to our Corporate Secretary prior to the meeting. Such notice shall set forth (a) as to each person whom the stockholder proposes to nominate for election or re-election as a director, (i) the name, age, business address and residence address of each such person, (ii) the principal occupation or employment of such person, (iii) the class and number of shares of Longeveron common stock that are beneficially owned by such person and (iv) any other information relating to such person that is required to be disclosed in solicitations of proxies for election of directors, or is otherwise required, in each case pursuant to Regulation 14A under the Exchange Act (including, without limitation, such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected); and (b) as to the stockholder giving the notice (i) the name and address of such stockholder as they appear on our books and (ii) the class and number of shares of Longeveron common stock that are beneficially owned by such stockholder. There are no differences in the manner in which the Nominating and Corporate Governance Committee evaluates a candidate that is recommended for nomination for membership on our Board by a stockholder. There have been no material changes to the procedures by which stockholders may recommend nominees to our Board since the last time we provided the foregoing disclosure.

Science and Strategy Committee. The Science and Strategy Committee is comprised of three members: Dr. Hajjar (chair), Dr. Hare and Dr. Paletta. The Science and Strategy Committee's purpose is to review and advise the full Board and the management of the Company with respect to scientific direction and opportunities deemed beneficial to the Company. The Science and Strategy Committee's responsibilities include reviewing the scientific basis of the Company's clinical programs, new products, or research areas under consideration by the Company, suggesting opportunities to refine or advance the Company's therapeutic technologies, and advising the Company in consultation with management on resource allocation for new product avenues. The Board has adopted and approved a written charter for the Science and Strategy Committee. A current copy of this charter is posted on our website at *http://www.longeveron.com* under the Investor Relations section. The Science and Strategy Committee held one (1) meeting during 2025.

Board Member Independence

The Board of Directors has determined that each of Dr. Hajjar, Ms. Ungaro, and Dr. Paletta are independent as defined in the Nasdaq Stock Market listing standards and applicable SEC regulations. Dr. Hare and Mr. Soffer have been determined not to be independent under relevant standards.

Executive Sessions

Independent directors meet in executive session without the presence of our non-independent directors or members of management to review the criteria upon which the performance of the CEO are measured, to review the performance of the CEO against those criteria, to ratify the compensation of the CEO as approved by the Compensation Committee, and to discuss any other relevant matters.

Board Leadership Structure

The Board's current leadership structure is characterized by:

- a combined Executive Chairman of the Board and Chief Science Officer;
- a robust Committee structure with oversight of various types of risks; and
- an engaged and majority independent Board.

The Board believes that its current leadership structure provides appropriate Board leadership and engagement while deriving the benefits from having our CSO also serve as Executive Chairman of the Board. As an individual with primary responsibility for managing the Company's scientific operations and in-depth knowledge and understanding of the Company as its co-founder, he is best positioned to chair regular Board meetings as we discuss key business and strategic issues. This combined structure provides independent oversight while avoiding unnecessary confusion regarding the Board's oversight responsibilities and the day-to-day management of business operations. We do not have a lead independent director.

Risk Oversight

Our Board oversees an enterprise-wide approach to risk management, designed to support the achievement of our strategic and organizational objectives, improve long-term organizational performance and enhance stockholder value. A fundamental part of risk oversight is to understand the risks our Company faces and the steps management is taking to manage those risks and to assess management's overall appetite for risk. It is management's responsibility to manage risk and bring material risks facing our Company to the Board's attention. Our Board receives regular reports from management on matters relating to strategic and operational initiatives, financial performance and legal developments which are each integrated with enterprise-risk exposures. Our Board also approves our CEO's performance goals for each year. In doing so, the Board has an opportunity to ensure that the CEO's goals include responsibility for broad risk management. The involvement of the full Board in setting our strategic plan is a key part of its assessment of the risks inherent in our corporate strategy.

The Committees of the Board are also involved in evaluating and overseeing the management of risks particular to their respective areas of oversight. For example, the Audit Committee focuses on financial risk and internal controls, supports the Board's oversight of cybersecurity risk management, and receives an annual risk assessment report from our external auditors. The Compensation Committee evaluates and sets compensation programs that encourage decision-making predicated upon a level of risk-taking consistent with our business strategy. The Compensation Committee also reviews compensation and benefit plans, and the risks associated with them. The Nominating and Corporate Governance Committee oversees governance and succession risk and evaluates director skills and qualifications to appoint particular directors to our standing committees based upon the needs of that committee. Each Committee reports its activities to the full Board to ensure that the Board is regularly informed about these risks.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, executive officers and directors. We will provide a copy of the Code of Business Conduct and Ethics (without charge) upon request made in writing to Longeveron Inc. at 1951 NW 7th Avenue, Suite 520, Miami, Florida 33136, Attention: Investor Relations. The full text of our Code of Business Conduct and Ethics is posted on our website at *www.longeveron.com* under the Corporate Governance Documents section. We intend to disclose any amendment to the Code of Business Conduct and Ethics or waiver of a provision of the Code of Business Conduct and Ethics applicable to our executive officers or directors, including the name of the executive officer or director to whom the amendment applies or for whom the waiver was granted, at the same location on our website identified above. The inclusion of our website address herein does not include or incorporate by reference the information on our website into this 10-K.

Board Communications

Stockholders may communicate with members of the Board of Directors by mail addressed to the full Board, a specific member of the Board or a particular committee of the Board at our principal executive offices located at 1951 NW 7th Avenue, Suite 520, Miami, Florida 33136, Attention: Legal Department.

Insider Trading Policy; Hedging Prohibition

The Company has adopted a Statement of Policy on Insider Trading (the "insider trading policy" or "insider trading policy guidelines") that describes our standards regarding the prohibition on trading, and causing the trading of securities while in possession of certain material nonpublic information, which the Company believes are reasonably designed to promote compliance with insider trading laws, rules and regulations, as well as any listing standards

applicable to the Company (including Nasdaq listing standards). Our insider trading policy is applicable to all of our directors, officers, employees, consultants, certain of their family members, and entities under the control of such persons. The policy attempts to establish standards that will avoid even the appearance of improper transactions on the part of insiders to preserve the Company's reputation for adhering to the highest standards of conduct.

The insider trading policy guidelines, among other things, prohibit the unauthorized disclosure of material nonpublic information about the Company or any company with which the Company deals. The insider trading policy prohibits trading in Company securities or "tipping" on the basis of material nonpublic information. These guidelines also provide certain specific exceptions for various transactions including, for example, (i) stock option exercises where no sale is made, (ii) the vesting of restricted stock awards or tax withholding requirements in connection therewith, (iii) bona fide gifts of securities, and (iv) Rule 10b5-1 plans. The insider trading policy further restricts trading and other transactions for a limited group of designated persons, including, for example, members of our Board of Directors, executive officers, and employees during certain "Blackout Periods" that follow the end of a given fiscal period. These designated persons are also required to pre-clear any trades in the Company's securities in accordance with the insider trading policy.

Our insider trading policy guidelines further acknowledge that short sales, buying or selling publicly traded options, hedging transactions in the Company's stock (including prepaid variable forwards, equity swaps, collars and exchange funds), margin accounts, pledged securities and standing and limit orders (outside of an approved Rule 10b5-1 plan) may permit a holder to continue to own our common stock obtained through benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, our directors, employees, and officers to whom our policy applies, may no longer have the same objectives as our other stockholders. As such, the Company's employees, consultants and directors are prohibited from engaging in such transactions (except as otherwise may be approved in writing by the Company).

A copy of the Longeveron Inc. insider trading policy is filed as Exhibit 19.1 to this Form 10-K.

Delinquent Section 16(a) Reports

The Company's directors and executive officers are required under Section 16(a) of the Exchange Act to file reports of ownership and changes in ownership of the Company's common stock with the SEC. Based upon a review of filings with the SEC and written representations from our directors and executive officers, we believe that all of our directors and executive officers complied during fiscal 2025 with the reporting requirements of Section 16(a) of the Exchange Act, with the exception of the following: (i) a Form 3 filed on October 1, 2025 for J. Nathaniel Powell, who was appointed interim CEO of the Company effective September 4, 2025; (ii) a Form 4 filed on October 1, 2025 reporting the September 4, 2025 grants of 50,000 restricted stock units and stock options exercisable for 20,000 shares of Class A common stock to J. Nathaniel Powell; (iii) a Form 3 filed on October 27, 2025 for Dr. George Paletta, Jr., who was appointed to the Board of Directors effective October 1, 2025; and (iv) a Form 4 filed on October 27, 2025 reporting the October 1, 2025 grant of 34,000 restricted stock units to Dr. George Paletta, Jr.

Item 11. Executive Compensation

The Summary Compensation Table below summarizes the compensation of the executive officers named therein (our "named executive officers" or "NEOs") during 2025 and 2024. Our NEOs for 2025 are as follows:

- J. Nathaniel Powell, former Interim Chief Executive Officer (CEO)
- Wa'el Hashad, former Chief Executive Officer (former CEO)
- Lisa A. Locklear, Chief Financial Officer (CFO) and Treasurer
- Paul Lehr, General Counsel and Corporate Secretary

Wa'el Hashad served as the Company's Chief Executive Officer until his departure on August 27, 2025. J. Nathaniel Powell served as the Company's Interim Chief Executive Officer from September 4, 2025 until his resignation from this role on February 9, 2026. The Board has appointed Stephen H. Willard to serve as the permanent Chief Executive Officer, effective February 11, 2026. The principal elements of our executive compensation program are base salary, discretionary annual performance bonuses, and discretionary equity awards. Our NEOs are also entitled

to participate in employee benefit plans and programs that we offer to our other employees, as described below. We view these components of compensation as related but distinct. Although our Compensation Committee does review total compensation, we do not believe that significant compensation derived from one component of compensation should negate or offset compensation from other components. Our executive compensation program is designed to attract, motivate, and retain talented and dedicated executive officers, who are critical to our success. The following highlights our approach to executive compensation:

Competitive Positioning: We seek to establish the overall compensation of our executive officers at levels that we believe are roughly comparable with the average levels of compensation of executives at other clinical state biotechnology companies of similar size.

Annual Bonus Compensation Tied to Performance: Our executive compensation program has three primary components: base salary; discretionary annual bonus compensation; and discretionary equity compensation; and other benefits and perquisites. Among these components, bonus compensation is tied in whole or in part to individual performance, company performance, or as otherwise determined appropriate by the Compensation Committee.

Equity-Based Incentives align our NEOs with our Stockholders: Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officers. The Compensation Committee of the Board is responsible for approving equity grants.

Base Salary Compensation. We pay our NEOs a base salary to compensate them for the satisfactory performance of services rendered to us. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries for our NEOs have generally been set at lower levels than would normally be deemed necessary to attract and retain individuals with this level of talent. For more information, see *Summary Compensation Table — 2025 and 2024* on page 103 of this Form 10-K.

Bonus Compensation. In order to retain and motivate our named executive officers and other executives, from time to time the Board upon recommendation of our Chief Executive Officer, may approve bonuses for our NEOs based on individual performance, company performance, or as otherwise determined based on the Compensation Committee's discretion. Estimated bonus amounts earned in 2025 and made under our executive incentive plan are reported in the "Non-equity incentive plan compensation" column of the Summary Compensation Table. For more information, see *Summary Compensation Table — 2025 and 2024* on page 103 of this Form 10-K.

Equity Compensation. We believe that for growth companies in the biotechnology sector, such as Longeveron, equity awards are a significant compensation-related motivator in attracting and retaining executive-level employees. Accordingly, we have provided our named executive officers and other executives with certain equity incentive awards that vest over several years to incentivize those individuals to stay with us, which in turn should provide us with greater stability over such periods than we would experience without such awards. Equity awards are granted for both restricted stock units and stock options, typically vesting quarterly over a three-year period. In 2024, restricted stock unit awards were granted to our named executive officers and other executives and employees that vested in full upon grant, to provide a one-time catch up grant for past initial hire grants that were not in line with current award levels.

Cash-to-Equity Program. In May 2024, we approved a program to allow our executive officers and directors the option to receive, on a quarterly basis, a portion of their respective cash compensation (up to a maximum of 80%) in the form of equity. In January 2025, we approved the expansion of this program to include stock options as a form of equity which directors and executive officers could elect to receive in lieu of cash compensation. In April 2025, we re-authorized the program on an ongoing basis (the "Cash-to-Equity Program"). The Cash-to-Equity Program allows for participating directors and executive officers to elect to equity or stock options in lieu of cash compensation at a premium equivalent valuation ranging from 125% to 200% of the individual's respective cash compensation, depending on the individual's level of Cash to-Equity Program election. All stock options granted pursuant to the Cash-to-Equity Program are fully exercisable as of the date of issuance. Further, all stock options granted under the Cash-to-Equity program are adjusted by the application of a Black-Scholes multiplier, as adjusted annually. In September 2025, the Company modified the Cash-to-Equity Program to remove the premium valuations, formerly ranging from 125% to 200%, but continuing the adjustment by the application of a Black-Scholes multiplier,

as determined and adjusted annually, for equity taken in the form of stock options. While the details of each quarterly payout under the Cash-to-Equity program are subject to the confirmation of our executive management team, any equity received by executive officers or directors pursuant to the Cash-to-Equity Program are subject to any applicable restrictions under the Longeveron Inc. Statement of Policy on Insider Trading as well as any restrictions pursuant to federal and state securities laws. Dr. Hare and Mr. Lehr took equity in lieu of cash under the Cash-to-Equity Program in 2025.

Other Elements of Compensation

Perquisites, Health, Welfare and Retirement Benefits. Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on generally the same basis as all of our other employees. We provide a 401(k) Plan to our employees, including our current named executive officers, as discussed in the section below titled "401(k) Plan."

401(k) Plan. We maintain a defined contribution employee retirement plan, or 401(k) Plan, for our employees. Our named executive officers are eligible to participate in the 401(k) Plan on the same basis as our other employees, if they are considered an employee and not a consultant. The 401(k) Plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan provides that each participant may make pre-tax deferrals from his or her compensation up to the statutory limit, which is $23,500 for calendar year 2025, and other testing limits. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2025 may be up to an additional $7,500 above the statutory limit. In addition, participants that are ages 60 to 63 can make "catch-up contributions" up to $11,250 (in lieu of $7,500) over the $23,500 statutory limit in calendar year 2025. The 401(k) Plan provides for discretionary matching and profit-sharing contributions; we currently provide 5% match to the 401(k) Plan. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

Deferred Compensation

Deferred Compensation Agreement. In 2024, we entered into a deferred compensation agreement with Dr. Hare to defer payment of the consulting fees earned by him for services rendered as our Chief Science Officer during 2024 totaling $265,000 plus interest shall mean a rate equal to the prime rate as published in the Wall Street Journal, as reported on the last day of each calendar year (or other applicable period if interest is credit more frequently). Furthermore, Dr. Hare timely elected to defer payment of any portion of consulting fees and incentive compensation earned for services rendered during 2025 in excess of $240,000. The 2024 consulting fees will be paid in the form of a lump sum distribution in February 2027. The 2025 consulting fees will be paid in the form of a lump sum distribution in February 2028.

Non-Qualified Deferred Compensation Plan. In April 2025, we adopted the Longeveron Inc. Non-Qualified Deferred Compensation Plan (the "NQDC Plan"), a non-qualified investment plan offered to our senior executive officers. Under our NQDC Plan, eligible executives may elect to defer up to 100% of their annual base salary and annual cash incentive bonus. Participants may elect to enroll in the NQDC Plan each year by timely making a deferral election, which deferral elections must generally be made prior to the start of each plan year and remain in-force for the duration of the plan year. In addition, the Company may make a discretionary contribution to the NQDC Plan on account of eligible participants. Participants' accounts are credited with earnings based on the gains or losses of a select group of hypothetical investment funds made available to participants under the NQDC Plan. The NQDC Plan is unfunded, unsecured and all benefits thereunder remain subject to the general unsecured creditors of the Company. The NQDC Plan offers two distribution accounts, a retirement account ("Retirement Accounts") and an in-service account ("In-Service Accounts"), each of which has its own timing and payment alternatives. Amounts held under Retirement Accounts are paid either in a lump sum or up to 15 annual installments upon reaching normal retirement age (age 65). Amounts allocated to In-Service Accounts are payable in a lump sum in January of the year specified. In the event a participant separates from service prior to reaching normal retirement age or the date specified for an In-Service Account, the participant's accounts will be paid in a lump sum or up to 15 annual installments in accordance with the participant's separation from service distribution election. If an eligible participant is a "specified employee" as defined in Section 409A of the Code, then any amounts payable to the participant under the NQDC Plan on account of the participant's separation from service will be delayed and paid promptly following the first day that is six months after the date the participant separated from service. Except for

the foregoing, we do not maintain any other nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our Board may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Cost Reduction Measures

On February 9, 2026, in connection with the ongoing review of its cash runway and cost structure, and following Board approval, the Company implemented a temporary 50% reduction in the compensation of the Company's CEO and its Executive Chairman/CSO. A temporary 25% reduction in the compensation of the Company's C-suite officers was also implemented. The Company is undertaking these compensation reductions as part of other cost-savings efforts. The Company currently anticipates that such compensation will be restored to the amounts in effect immediately prior to such reductions at such time as the Company secures sufficient financing or other sources of capital.

The Company currently intends, subject to a good-faith determination of its financial ability to do so, to repay the members of the Company's executive leadership team an amount equal to the difference between such executive's base salary in effect immediately prior to the reduction and the reduced salary paid during the applicable reduction period. Any such repayment is not guaranteed and shall be solely at the Company's discretion, contingent upon the Company's financial condition. In consideration of the reduction and each executive's continued service, subject to approval of the Board (or an applicable committee thereof), the Company intends to grant each executive an aggregate of 50,000 restricted stock units, which shall vest on or around June 1, 2026, in accordance with the terms of the Company's Third Amended and Restated 2021 Incentive Award Plan.

Summary Compensation Table — 2025 and 2024

Name and principal position	Year	Salary ($)	Stock awards ($)[2]	Option awards ($)[3]	Non-equity incentive plan compensation ($)[4]	All other compensation ($)[5]	Total ($)
J. Nathaniel Powell	2025	194,386	112,225	10,632	135,550	23,031	475,824
Former Interim Chief Executive Officer	2024	—	—	—	—	—	—
Wa'el Hashad[1]	2025	482,180	264,600	65,550	—	468,922	1,281,252
Former Chief Executive Officer	2024	570,973	765,675	70,725	389,550	51,816	1,848,739
Lisa A. Locklear,	2025	431,693	149,940	37,145	199,350	43,960	862,087
Chief Financial Officer and Treasurer	2024	430,923	429,885	39,975	189,000	33,468	1,123,251
Paul Lehr,	2025	419,975	337,439	37,145	193,950	61,006	1,049,516
General Counsel and Corporate Secretary	2024	420,150	438,207	39,975	184,275	144,089	1,226,696

(1) Effective September 9, 2025, Mr. Hashad's employment with the Company was terminated. Under the terms of his separation agreement, Mr. Hashad is entitled to receive twelve (12) months of base salary amounting to $585,000 and paid on a bi-weekly basis over 12 months, of which $135,000 was paid as of December 31, 2025, COBRA coverage for 18 months, a bonus payment of $282,723 prorated based on date of termination that was paid in October 2025, and accelerated vesting of 60,521 restricted stock units and 79,166 stock options in October 2025.

(2) The values set forth in this column are based on the aggregate grant date fair values of 2025 Restricted Stock Unit (RSU) awards computed in accordance with FASB ASC Topic 718. The grant date fair values of RSUs are computed based on the closing price per share of Longeveron Class A common stock on the date of grant. A discussion of the relevant assumptions made in the valuation of these awards is provided in Note 8 to the financial statements, Equity Incentive Plan, in this Form 10-K.

(3) The values set forth in this column represent the aggregate grant date fair value of stock option awards computed in accordance with FASB ASC Topic 718 (excluding the effect of estimated forfeitures). A discussion of the relevant assumptions made in the valuation of these awards is provided in Note 8 to the financial statements, Equity Incentive Plan, in this Form 10-K.

(4) Includes performance payouts at target for Company performance in 2025 under our executive incentive plan, described as "Bonus Compensation" in the narrative above. The relevant performance measures for the annual performance awards were satisfied and thus reportable in 2025, even though final performance payout will be calculated and approved by the Compensation Committee in March 2026.

(5) Other compensation represents 401(k) matching, health insurance costs and life and disability insurance paid by the Company. For Mr. Lehr, in 2025 this includes medical insurance of $28,385.

Outstanding Equity Awards at Fiscal Year End Table - 2025

The following table sets forth information with respect to outstanding equity awards for each of our NEOs as of December 31, 2025. Note that all amounts set forth herein have been adjusted, as necessary, to reflect the Company's one-for-ten reverse stock split implemented in March of 2024.

	Options Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[1]
J. Nathaniel Powell,	—	20,000	0.75	9/4/2035[3]	53,166	27,115[4]
Former Interim Chief Executive Officer					50,000	25,500[5]
Wa'el Hashad,[2]						
Former Chief Executive Officer						
Lisa A. Locklear,	6,771	9,479	2.46	8/15/2034[6]	32,500	16,575[8]
Chief Financial Officer and Treasurer	2,834	31,166	1.47	7/15/2035[7]	28,437	14,503[9]
					93,500	47,685[10]
Paul Lehr,	5,000		60.80	7/20/2031[11]	28,437	14,503[8]
General Counsel and Corporate Secretary	500		87.30	6/3/2032[12]	93,500	47,685[10]
	2,143	142	43.00	11/16/2032[13]		
	6,771	9,479	2.46	8/15/2034[6]		
	2,834	31,166	1.47	7/15/2035[7]		

(1) Based on the value of $0.51 per share, the closing market price of our common stock on December 31, 2025.

(2) Effective September 9, 2025, Mr. Hashad's employment with the Company was terminated. Under the terms of his separation agreement, Mr. Hashad is entitled to receive twelve (12) months of base salary amounting to $585,000 and payable bi-weekly over 12 months, of which $135,000 was paid as of December 31, 2025, COBRA coverage for 18 months, a bonus payment of $282,723 prorated based on the date of his termination which was paid in October 2025, and accelerated vesting of 60,521 restricted stock units and 79,166 stock options in October 2025. As a result of Mr. Hashad's separation from service, he did not have any equity awards outstanding as of December 31, 2025.

(3) The option fully vests one year from the grant date, which will be September 4, 2026.

(4) Restricted Stock Unit awards granted on July 7, 2025, vests quarterly over three years beginning on October 1, 2025.

(5) Restricted Stock Unit awards granted on September 4, 2025, vests one year from the grant date, which will be September 4, 2026.

(6) The option, granted on August 15, 2024, vests quarterly over three years beginning on October 1, 2024.

(7) The option, granted on July 15, 2025, vests quarterly over three years beginning on October 1, 2025.

(8) Restricted Stock Unit awards granted on August 15, 2024, vests quarterly over three years beginning on October 1, 2024.

(9) Restricted Stock Unit awards granted on August 15, 2024, vests quarterly over various periods up to two years beginning on October 1, 2024.

(10) Restricted Stock Unit award granted on July 15, 2025, vests quarterly over 3 years beginning on October 1, 2025.

(11) The option, granted July 20, 2021, vested one-eighth on the date of grant, with quarterly vesting thereafter.

(12) The option, granted June 3, 2022, was fully vested upon grant.

(13) The option, granted November 16, 2022, vests 25% on March 1, 2023, then 6.25% each quarter thereafter.

Grants of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

Our policies and practices regarding the grant of equity awards are designed to comply with applicable securities laws to and reflect the integrity of our executive compensation program. The Compensation Committee is responsible for determining the timing and terms of equity awards to eligible personnel. The timing of equity award grants is determined with consideration to a variety of factors, including ensuring that the Company is not in possession of material nonpublic information at the time of grant. While the Company's equity compensation program seeks alignment with the Company's strategic objectives, competitive aims, and the attraction and retention of qualified personnel, the equity compensation of each individual is generally considered on a case-by-case basis. The Company does not follow a predetermined schedule for the granting of all equity awards. Nevertheless, certain of the Company's equity awards adhere to standard award timelines and vesting schedules.

We do not grant equity awards in anticipation of the release of material nonpublic information and do not time the public release of such information based on equity award grant dates for the purpose of affecting the value of executive compensation. However, the Compensation Committee may consider material nonpublic information to ensure that grants of equity awards comply with applicable laws and regulations as well as Company policy. The Company's procedures to prevent the improper use of material nonpublic information in connection with the granting of equity awards include oversight by internal and external legal counsel. We are committed to maintaining equity compensation practices that comply with evolving corporate governance standards, foster a competitive workforce, and serve the best interests of the Company and its stockholders.

Employment Agreements/Letters with our NEOs

Ms. Lisa A. Locklear. On July 14, 2023, the Company entered into a letter agreement ("Agreement") with Ms. Lisa A. Locklear and hired her as Chief Financial Officer and Executive Vice President of the Company. Ms. Locklear receives an annual salary of $420,000 and is eligible to receive an annual cash bonus of up to forty-five percent (45%) of her base salary, eighty percent (80%) of which will be based on the achievement of pre-established performance criteria and twenty percent (20%) of which will be based on pre-established individual performance criteria. Ms. Locklear received a signing bonus of 4,000 Restricted Stock Units, which vested in quarterly installments on each of October 1, 2023, January 1, 2024, April 1, 2024, and July 1, 2024. Ms. Locklear will also be eligible to receive up to 10,000 performance share units annually, eighty percent (80%) of which will be based on the achievement of pre-established performance criteria and twenty percent (20%) of which will be pre-established individual performance criteria. Share numbers have been adjusted for the March 26, 2024 Reverse Split discussed in Note 2 to the financial statements, Summary of Significant Accounting Policies, in this 10-K.

Upon termination of employment, Ms. Locklear shall be entitled to receive accrued salary and benefits, unless terminated without Cause (as defined therein) or by Ms. Locklear for Good Reason (as defined therein), in which event, in addition to accrued amounts, Ms. Locklear shall also be entitled to receive earned but unpaid equity bonus amounts, an annual prorated cash bonus payment at target level, plus severance and reimbursement of COBRA premiums equal to three (3) months of base salary and premiums for each full year worked at the Company (not less than six months in any case), in all cases only if a release is executed and not revoked. Ms. Locklear also entered into a Confidentiality and Nondisclosure Agreement simultaneously with this Agreement that imposed certain confidentiality, non-competition, non-disclosure obligations on her.

Mr. Paul Lehr. On March 14, 2024, the Company entered into a new letter agreement ("Agreement") with Mr. Lehr, who has served as the Company's General Counsel since 2016. Pursuant to the Agreement, Mr. Lehr receives an annual salary of $390,000 and is eligible to receive an annual cash bonus of up to thirty-five percent (35%) of his base salary, eighty percent (80%) of which will be based on the achievement of pre-established performance criteria and twenty percent (20%) of which will be based on pre-established individual performance criteria. Subsequently, the Compensation Committee revised the threshold potential annual cash bonus level to forty-five percent (45%) of base salary. Mr. Lehr will also be eligible to receive up to 10,000 performance share units annually, eighty percent (80%) of which will be based on the achievement of pre-established performance criteria and twenty percent (20%) of which will be based on pre-established individual performance criteria. Share numbers have been adjusted for the March 26, 2024 Reverse Split discussed in Note 2 to the financial statements, Summary of Significant Accounting Policies, in this 10-K.

Upon termination of employment, Mr. Lehr shall be entitled to receive accrued salary and benefits, unless terminated without Cause (as defined therein) or by Mr. Lehr for Good Reason (as defined therein), in which event, in addition to accrued amounts, Mr. Lehr shall also be entitled to receive earned but unpaid equity bonus amounts, an annual prorated cash bonus payment at target level, plus severance and reimbursement of COBRA premiums equal to three (3) months of base salary and premiums respectively for each full year worked at the Company, in all cases only if a release is executed and not revoked. Mr. Lehr also entered into a Confidentiality and Nondisclosure Agreement simultaneously with this Agreement that imposed certain confidentiality, non-competition, non-disclosure obligations on him.

On May 6, 2024, the Compensation Committee approved, and on August 15, 2024, the Company issued certain additional equity awards to executive officers and other employees of the Company that served to recalibrate the equity holdings of those employees, as well as additional bonus discretionary equity awards above what was otherwise contractually owed pursuant to the terms of each individual's employment agreements. On June 12, 2025 the Compensation Committee approved, and on July 15, 2025, the Company issued annual discretionary equity awards to executive officers and other employees of the company above what was otherwise contractually owed pursuant to the terms of each individual's employment agreements.

Separation Severance and Other Agreements with our Former NEOs

Mr. Wa'el Hashad. Effective September 9, 2025, Mr. Hashad's employment with the Company was terminated. Under the terms of his separation agreement, Mr. Hashad is entitled to receive twelve (12) months of base salary amounting to $585,000 and payable bi-weekly over 12 months, of which $135,000 was paid as of December 31, 2025, COBRA coverage for 18 months, a bonus payment of $282,723 prorated based on the date of his termination which was paid in October 2025, and accelerated vesting of 60,521 restricted stock units and 79,166 stock options in October 2025. As a result of Mr. Hashad's separation from service, he did not have any equity awards outstanding as of December 31, 2025.

Mr. J. Nathaniel Powell. On February 9, 2026, Mr. Powell resigned from his role as Interim Chief Executive Officer of the Company and agreed to revert to his former business development role with the Company as a consultant. Pursuant to the terms of the letter agreement dated September 3, 2025, ("Agreement") setting forth Mr. Powell's compensation during his tenure as Interim Chief Executive Officer of the Company starting on September 4, 2025, Mr. Powell was entitled to receive an annual salary of $500,000 with eligibility for an annual cash bonus of up to sixty percent (60%) of his base salary, eighty percent (80%) of which would have been based on the achievement of pre-established performance criteria and twenty percent (20%) of which would have been discretionary. Mr. Powell received a one-time grant of 50,000 Restricted Stock Units and 20,000 stock options, and such awards would have vested on September 4, 2026, had he remained an employee of the Company. Under the terms of his consulting agreement, Mr. Powell will receive 100,000 shares of Class A common stock upon achievement of certain milestones, as defined in the agreement.

Potential Payments Upon Termination or Change in Control

The terms of the Company's Third Amended and Restated 2021 Incentive Award Plan (the "Plan") provide that the shares subject to vesting granted under any equity award may automatically become fully vested, no longer subject to restrictions and freely transferable upon a "Change of Control" as such term is defined in our Plan. We provide this benefit in order to properly incentivize our executives to support a Change of Control that would be deemed beneficial to our stockholders.

DIRECTOR COMPENSATION

Director Compensation Table — 2025. The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our non-employee directors for services rendered during the year ended December 31, 2025. Mr. Hashad, the Company's former Chief Executive Officer, did not receive any additional compensation for previously serving as a member of the Board of Directors.

	Fees earned or paid in cash ($)[1]	Stock Awards ($)[2]	Option Awards ($)[3]	All Other Compensation ($)	Total ($)
Joshua M. Hare, M.D.[4]	—	—	—	523,009[5]	523,009
Neil E. Hare[6]	3,266	—	—	—	3,266
Rock Soffer	45,000	24,990	—	—	69,990
Ursula Ungaro	63,700	24,990	—	—	88,690
Khoso Baluch[7]	56,315	24,990	—	—	81,305
Richard Kender	65,550	24,990	—	—	90,540
Neha Motwani[7]	49,916	24,990	—	—	74,906
Roger Hajjar, M.D.	62,817	24,990	—	—	87,807
George Paletta, Jr., M.D.[8]	13,156	31,178	—	—	44,334

(1) Amounts reflect fees paid relating to calendar 2025.

(2) The values set forth in this column represent the aggregate grant date fair value, computed in accordance with FASB ASC Topic 718 (excluding the effect of forfeitures), of the Board of Directors restricted stock unit awards granted on July 15, 2025. Additionally, Dr. Paletta received an onboarding restricted stock award on October 1, 2025. A discussion of the relevant assumptions made in the valuation of these awards may be found in Note 8 to the financial statements, Equity Incentive Plan, in this Form 10-K. The number of unvested restricted stock units and unvested stock option awards outstanding as of December 31, 2025 was as follows:

	Unvested Stock Awards	Unvested Option Awards
Joshua M. Hare, M.D.	—	104,432
Rock Soffer	20,249	725
Ursula Ungaro	20,249	725
Richard Kender	23,583	—
Roger Hajjar, M.D.	24,916	—
George Paletta, Jr. M.D.	34,000	—

(3) Dr. Hare was the only director to receive stock options in 2025. Such options were received in connection with his service as Chief Science Officer of the Company, pursuant to the terms of that certain consulting agreement entered into with the Company and are accordingly included in "All Other Compensation." For additional information, see "Part III. Item 13. Certain Relationships and Related Party Transactions."

(4) Amounts set forth herein reflect compensation received as a director of the Company. "All Other Compensation" also includes compensation that Dr. Hare receives as the Chief Science Officer of the Company, pursuant to the terms of that certain consulting agreement entered into with the Company. For additional information, see "Part III. Item 13. Certain Relationships and Related Party Transactions."

(5) Includes compensation received as the Chief Science Officer of the company, pursuant to his consulting agreement. In 2025, this compensation includes consulting fees of $284,677, estimated 2025 incentive compensation award of $119,250, and stock option awards totaling $119,082 related to his consulting services. In 2025, we continued a deferred compensation agreement with the CSO to defer payment of a portion of his consulting fees earned for services rendered as our Chief Science Officer during 2025 totaling $45,000. The 2025 consulting fees will be paid in the form of a lump sum distribution in February 2028.

(6) Mr. Neil Hare resigned from the Board on January 27, 2025.

(7) Ms. Motwani and Mr. Baluch resigned from the Board on November 7, 2025, and, as a result, each director forfeited 15,583 unvested restricted stock unit awards that were granted in 2025.

(8) Dr. Paletta was appointed to the Board of Directors to fill a vacancy on October 1, 2025.

Summary of Director Compensation

The director compensation program provides for annual retainer fees and/or long-term equity awards for our directors. For 2025, each director received an annual retainer of $45,000. A director serving as chairman of the Board received an additional annual retainer of $20,000. Directors serving as the chairs of the Audit, Compensation, Nominating and Corporate Governance, and Science & Strategy committees received additional annual retainers of $15,000, $12,000, $10,000, and $7,500, respectively. Directors serving as members of the Audit, Compensation, Nominating and Corporate Governance and Science & Strategy committees received additional annual retainers of $8,000, $6,000, $5,500 and $5,000, respectively. Annual equity grants, to be made following the Company's annual meeting of stockholders, are currently 17,000 restricted stock units for each director, and initial grants upon joining the Board in 2025 are 34,000 restricted stock units of our Class A common stock, which shall be subject to vesting requirements. The annual retainers and annual equity grant award amounts are subject to change upon approval of the Compensation committee.

Since May 2024, the Company's directors are also eligible to participate in the Company's Cash-to-Equity Program. For additional information on the Cash-to-Equity Program, see *Executive Compensation — Cash-to-Equity Program.*

Our Board or its authorized committee may modify the director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, subject to the annual limit on director compensation set forth in the Plan. As provided in the Plan, our Board or its authorized committee may make exceptions to this limit for individual directors in extraordinary circumstances, as the Board or its authorized committee may determine in its discretion.

The Company is currently undertaking certain cost-savings efforts, which include a reduction in Board of Directors' fees. Such reductions became effective on or about February 16, 2026. The Company currently anticipates that such compensation will be restored to the amounts in effect immediately prior to such reductions at such time as the Company secures sufficient financing or other sources of capital.

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

The following table sets forth certain information known to us as of March 9, 2026 (except where another date is noted below), with respect to beneficial ownership of our Common Stock by (i) each person (or group of affiliated persons) who is known by us to own beneficially more than five percent (5%) of our outstanding Common Stock and is not a director or executive officer, (ii) each of our named executive officers and current directors, and (iv) all current directors and executive officers as a group, together with the approximate percentages of outstanding Common Stock owned by each of them.

The following table is based upon information supplied by directors, executive officers, and principal stockholders. Beneficial ownership has been determined in accordance with Rule 13d-3 under the Exchange Act. A person has beneficial ownership of shares if the person has the power to vote or dispose of such shares. This power can be exclusive or shared, direct or indirect. In addition, a person is considered by SEC rules to beneficially own shares underlying options and convertible securities that are presently exercisable or convertible or will become exercisable or convertible within 60 days of the date that beneficial ownership is calculated. Unless otherwise indicated the address of each beneficial owner is c/o Longeveron Inc., 1951 NW 7th Ave, Suite 520, Miami, FL 33136, and none

of the shares listed are pledged. The percentage of beneficial ownership is based on 21,783,749 shares of Class A common stock and 1,484,005 shares of Class B common stock as of March 9, 2026, as adjusted for underlying options and convertible securities that are presently exercisable or convertible or will become exercisable or convertible within 60 days of the date that beneficial ownership is calculated.

Name of Affiliate	Class A Common Stock Shares	% of Class	Class B Common Stock Shares	% of Class	% of Total Voting Power[1]	% of Total Common Stock Beneficially Owned
Greater than 5% Holder:						
The Estate of Donald M. Soffer[2]	15,851	*	653,523	44.0%	14.1%	2.9%
Lee Cohen Hare	—	*	298,483	20.1%	0%[3]	1.3%
Named Executive Officers and Directors						
Joshua M. Hare, M.D.[4]	742,449	3.3%	462,808	31.2%	19.3%[3]	5.1%
Rock Soffer[5]	308,164	1.4%	41,010	2.8%	2.2%	1.5%
Ursula Ungaro[6]	25,892	*	—	*	*	*
George Paletta, Jr., M.D.[7]	5,667	*	—	*	*	*
Roger Hajjar, M.D.[8]	13,583	*	—	*	*	*
Wa'el Hashad[9]	185,496	*	—	*	*	*
Lisa A. Locklear[10]	165,685	*	—	*	*	*
Paul Lehr[11]	273,983	1.3%	—	*	1.2%	1.2%
Nataliya Agafonova[12]	124,003	*	—	*	*	*
Devin Blass[13]	69,242	*	—	*	*	*
J. Nathaniel Powell[14]	71,470	*	—	*	*	*
All Executive Officers and Directors as a Group (10 individuals)[15]:	**1,848,135**	**8.2%**	**503,818**	**33.9%**	**25.0%**	**9.8%**

* Less than 1%.

(1) Percentage of total voting power represents voting power with respect to all shares of our common stock and Class B common stock, as a single class. The holders of our Class B common stock are entitled to five (5) votes per share, and holders of our common stock are entitled to one (1) vote per share.

(2) Shares held by the estate of Donald M. Soffer.

(3) Pursuant to a Voting Agreement and Proxy entered into between Dr. Hare and Lee Cohen Hare, Dr. Hare's former spouse holds 298,483 shares of Class B common stock, which are not included in the number of shares owned by Dr. Hare for purposes of this table, as he retains voting but not dispositive power with respect to such shares, for so long as such shares remain owned by his former spouse.

(4) Amount includes 342,368 stock options and 148,936 warrants that are exercisable within 60 days of March 9, 2026. Amount also includes 533 shares held by an affiliated entity. Dr. Hare disclaims beneficial ownership except to the extent of his pecuniary interest.

(5) Amount includes 2,083 restricted stock units that may vest and 975 stock options and 138,298 warrants that are exercisable within 60 days of March 9, 2026.

(6) Amount includes 2,083 restricted stock units that may vest and 975 stock options that are exercisable within 60 days of March 9, 2026.

(7) Amount includes 2,833 restricted stock units that may vest within 60 days of March 9, 2026.

(8) Amount includes 2,750 restricted stock units that may vest within 60 days of March 9, 2026.

(9) Amount includes 10,638 warrants that are exercisable within 60 days of March 9, 2026.

(10) Amount includes 23,396 restricted stock units that may vest and 17,980 stock options and 29,415 warrants that are exercisable within 60 days of March 9, 2026.

(11) Amount includes 12,563 restricted stock units that may vest and 25,765 stock options that are exercisable within 60 days of March 9, 2026.

(12) Amount includes 23,396 restricted stock units that may vest and 17,980 stock options that are exercisable within 60 days of March 9, 2026.

(13) Amount includes 19,333 restricted stock units that may vest and 8,500 stock options that are exercisable within 60 days of March 9, 2026.

(14) Amount includes 44,115 warrants that are exercisable within 60 days of March 9, 2026.
(15) Amount includes 12,500 restricted stock units that may vest and 12,500 stock options that are acquirable or exercisable within 60 days of March 9, 2026 by Mr. Willard, as well as restricted stock units, stock options and warrants acquirable or exercisable within 60 days of March 9, 2026 by Dr. Hare, Mr. Soffer, Ms. Ungaro, Dr. Paletta, Dr. Hajjar, Ms. Locklear, Mr. Lehr, Dr. Agafonova, and Mr. Blass.

Equity Compensation Plan Information

The following table summarizes information, as of December 31, 2025, for the equity compensation plans of the Company pursuant to which grants of options, restricted stock, restricted stock units or other rights to acquire shares may be granted from time-to-time:

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)(c)
Equity compensation plans approved by security holders[1]	658,187	$ 3.18	2,869,051[2]
Equity compensation plans not approved by security holders	—	—	—
Total	658,187	$ 3.18	2,869,051

(1) Represents outstanding awards pursuant to the Company's Third Amended and Restated 2021 Incentive Award Plan. Represents shares of Class A common stock. Shares of Class B common stock are not authorized for issuance under the Plan.
(2) Shares of Class A common stock that are subject to any award (e.g., options, restricted stock units, etc.) pursuant to the Plan will count against the aggregate number of shares of Class A common stock that may be issued as one share for every share issued.

Item 13. Certain Relationships and Related Transactions and Director Independence

The following includes a summary of transactions as of December 31, 2025 to which we have been a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock, or 5% security holders, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Employment and Consulting Agreements with our NEOs". We also describe below certain other transactions with our directors, executive officers and stockholders.

The following are the Company's related party transactions as of December 31, 2025:

CSO Consulting Services Agreements

On November 20, 2014, the Company entered into a ten-year consulting services agreement with our Chief Science Officer (CSO) and Executive Chairman, Dr. Joshua Hare, (the "Agreement") under which the Company has agreed to pay the CSO $265,000 annually for his part-time services. The Agreement acknowledged that Dr. Hare is employed by the University of Miami ("UM"), remains subject to UM's policies, and that he serves as a consultant to enumerated outside entities. The Agreement outlined Dr. Hare's obligations with respect to confidentiality, ownership of information, inventions and original works, contains a non-competition covenant with respect to Dr. Hare's associations during his time with the Company and for a period of two (2) years thereafter, and contains non-solicitation and non-disparagement obligations.

The initial term of the Agreement ended on November 22, 2024; however, with regard to the annual compensation paid to Dr. Hare, the Company continues at present to operate under the same terms on a month-to-month basis. In addition, the Company entered into a deferred compensation agreement with Dr. Hare to defer payment of the consulting fees earned for services rendered during 2024, which deferred consulting fees will be paid in a lump sum distribution in February 2027. A similar arrangement was also entered into for 2025. On March 4, 2025 and April 11, 2025, the Company entered into stock option agreements with the CSO as part of a Cash-for-Equity Program. These agreements represent settlement of (i) approximately $45,000 in previously accrued consulting fees, and (ii) the CSO's 2024 performance bonus of approximately $131,000, respectively. Pursuant to the Company's Cash-for-Equity Program, the CSO elected to receive this amount in the form of options to purchase 71,254 and 184,878 shares of the Company's Class A Common Stock, respectively. Each award fully vested on July 1, 2025, following stockholder approval at the Company's 2025 annual meeting of stockholders on June 13, 2025, increasing the pool of the shares available for awards under the 2021 Incentive Plan. On July 1, 2025, the Company entered into an additional stock option agreement with the CSO as part of the Cash-for-Equity Program, with such agreement representing settlement of $30,000 in consulting fees earned for services rendered during the three months ended June 30, 2025. Pursuant to the Cash-for-Equity Program, the CSO elected to receive this amount in the form of fully vested options to purchase 49,219 shares of the Company's Class A Common Stock. On July 15, 2025, the Company granted the CSO options to purchase 109,000 shares of the Company's Class A Common Stock at an exercise price of $1.47 per share, as part of his annual compensation package, with the options vesting quarterly over three years.

The Compensation Committee increased Dr. Hare's annual compensation to $350,000 effective January 2026.

JMHMD License Agreement

We are a licensee under an exclusive license agreement with JMH MD Holdings, LLC ("JMHMD"), an affiliate of our CSO and Executive Chairman, for the use of CD271 cellular therapy technology, a subpopulation of bone marrow-derived MSCs. We are required to pay JMHMD a running royalty in an amount equal to one percent of the annual net sales of the licensed product(s) used, leased, or sold by or for us by any sub-licensees, payable on a country-by-country basis beginning on the date of first commercial sale and ending on the latter of expiration of the last to expire patent rights in such country or ten years from the first commercial sale in such country (provided that if all claims within the patent rights have expired or been finally deemed invalid then the royalty will be reduced by 50%), and which may also be reduced to the extent the Company is required to pay royalties to a third party for the same product or process.

Under the agreement, the Company is required to use commercially reasonable efforts to achieve the following milestones: (i) submit an investigational new drug application to FDA (or international equivalent) within one year of the effective date of agreement, (ii) initiate a clinical trial utilizing bone marrow derived CD271+ Precursor Cells within three years of the effective date; provided, that any of the milestones may be extended for up to six months for a total of three times by notice and payment of a five thousand dollar extension fee. The agreement is to remain in effect until either the date all issued patents and filed patent applications have expired or been abandoned, or 20 years after the date of FDA approval of the last commercialized product or process arising from the patent rights, whichever comes later. If we sublicense the technology, we are also required to pay an amount equal to 10% of the net sales of the sub-licensees.

There were no license fees due during the years ended December 31, 2025 and 2024 pertaining to this agreement.

Participation in Capital Markets Transactions

On August 11, 2025, the Company closed a public offering of 5,882,354 shares of Class A Common Stock and pre-funded warrants, which were sold together with Class A common warrants to purchase up to 14,705,885 shares of Class A Common Stock. The combined public offering price was $0.85 per share of Class A Common Stock and related Class A Common Stock warrants and $0.849 per pre-funded warrant and related Class A Common Stock warrants. Mr. J. Nathaniel Powell, our former Interim Chief Executive Officer, Lisa A. Locklear, our current Chief Financial Officer, and Mr. Khoso Baluch, a former member of our Board of Directors, each participated in the transaction. However, the amount involved with such participation did not exceed $120,000.

Indemnification Agreements

We have indemnification agreements with each of our directors and executive officers. These agreements may require us, among other things, to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including some expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Policies and Procedures for Related Person Transactions

Our Board has adopted a written related person transaction policy, which sets forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section, except those certain transactions described under the heading "Participation in Capital Markets Transactions," occurred prior to the adoption of this policy. Those transactions described under the heading "Participation in Capital Markets Transactions" were approved in accordance with the terms of the policy.

Item 14. Principal Accountant Fees and Services

The following is a summary of the fees billed to Longeveron by CBIZ CPAs P.C.*, the Company's current independent auditors, for professional services rendered for the fiscal year ended December 31, 2025, and fees billed to Longeveron by Marcum LLP* for professional services rendered for the fiscal year ended December 31, 2024.

Fee Category	Fiscal 2025 Fees	Fiscal 2024 Fees
Audit Fees	$ 462,470	$ 510,716
Tax Fees	—	—
All Other Fees	—	—

* *On November 1, 2024, CBIZ CPAs P.C. ("CBIZ") acquired the attest business of Marcum LLP ("Marcum"). Substantially all of the partners and staff that provided attestation services with Marcum joined CBIZ.*

Audit Fees: This category includes the fees billed by our principal accountants for professional services rendered for the audit of our annual financial statements, the quarterly review of our interim financial statements, and services provided in connection with regulatory filings.

Audit-Related Fees: This category consists of assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported above under "Audit Fees."

Tax Fees: This category consists of fees billed for professional services rendered for tax compliance, tax advice and tax planning.

All Other Fees: This category consists of services billed not included in the categories above.

Audit Committee Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy that requires pre-approval of all audit services and permissible non-audit services to be provided by our independent registered public accounting firm, as required by the Exchange Act. The Audit Committee must approve the permitted service before the independent auditor is engaged to perform it. Under the policy, the Audit Committee pre-approves all audit and permissible non-audit services provided by our independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services and is subject to a specific budget. In addition, the Audit Committee may also pre-approve particular services on a case-by-case basis. For each proposed service, the independent registered public accounting firm is required to provide detailed back-up documentation at the time of approval. The Audit Committee may delegate pre-approval authority to one or more of its members. Such a member must report any decisions to the Audit Committee at the next scheduled meeting. The Audit Committee approved all of the services described above in accordance with its pre-approval policies and procedures.

PART IV

Item 15. Exhibits and Financial Statements Schedules

a. (1) Financial Statements:

The financial statements required to be filed by Item 8 of this Annual Report on Form 10-K and filed in this Item 15, are as follows:

(2) Financial Statement Schedules

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the financial statements and notes thereto.

(3) Exhibits

Exhibit Number	Description of Exhibit
2.1^	Plan of Conversion, incorporated by reference to Exhibit 2.1 to the Registrant's Annual Report on Form 10-K filed on March 30, 2021
2.2	Certificate of Conversion of Longeveron LLC, incorporated by reference to Exhibit 2.2 to the Registrant's Annual Report on Form 10-K filed on March 30, 2021
3.1	Certificate of Incorporation of Longeveron Inc., incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on February 16, 2021
3.2	Certificate of Amendment to Certificate of Incorporation of Longeveron Inc., incorporated by reference to Exhibit 3.1(a) to the Registrant's Current Report on Form 8-K filed March 19, 2024
3.3	Bylaws of Longeveron Inc., incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-8 filed on February 16, 2021
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 12, 2026
4.1	Specimen Class A Common Stock Certificate evidencing the shares of Class A Common Stock, incorporated by reference to Exhibit 4.1 on Registrant's Registration Statement No. 333-252234 filed February 3, 2021
4.2	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K filed on February 27, 2024
4.3	IPO Underwriter Warrants issued February 17, 2021, incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K filed on March 30, 2021
4.4	Form of PIPE Representative Warrant, incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed December 3, 2021
4.5	Form of Pre-Funded Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed October 13, 2023
4.6	Form of Series A/B Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed October 13, 2023.
4.7	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.3 to the Registrant's Current Report Form 8-K filed October 13, 2023.
4.8	Form of Common Stock Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed December 22, 2023.

Exhibit Number	Description of Exhibit
4.9	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed December 22, 2023.
4.10	Form of Pre-Funded Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed April 11, 2024
4.11	Form of Common Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed April 11, 2024
4.12	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed April 11, 2024
4.13	Form of Series C/D Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed April 18, 2024
4.14	Form of Placement Agent Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed April 18, 2024
4.15	Form of New Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 18, 2024
4.16	Form of Placement Agent Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed June 18, 2024
4.17	Form of Common Stock Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed July 19, 2024
4.18	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed July 19, 2024
4.19	Form of Ordinary Course Placement Agent Warrant, incorporated by reference to Exhibit 4.19 of the Registrant's Registration Statement on Form S-1 filed August 6, 2024
4.20	Form of Pre-Funded Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed August 11, 2025
4.21	Form of Common Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed August 11, 2025
4.22	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed August 11, 2025
4.23	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed March 12, 2026
10.1†	Exclusive License Agreement dated November 20, 2014 between the University of Miami and Longeveron LLC, incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.1.1	Amendment to Exclusive License Agreement dated December 11, 2017 between the University of Miami and Longeveron LLC, incorporated by reference to Exhibit 10.1.1 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.1.2	Second Amendment to Exclusive License Agreement dated March 3, 2021 between the University of Miami and Longeveron Inc., incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 9, 2021
10.2^	Collaborative Research and Development Agreement dated March 3, 2021 between the University of Miami and Longeveron Inc., incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed March 9, 2021
10.3†	License Agreement dated December 22, 2016 between JMHMD Holdings, LLC and Longeveron LLC, incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.3.1	First Amendment to License Agreement effective December 22, 2016, by and between JMHMD Holdings, LLC and Longeveron LLC, incorporated by reference to Exhibit 10.2.1 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.4#	Consulting Services Agreement, dated November 20, 2014, by and between Longeveron LLC and Joshua M. Hare, M.D., incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.5#	Consulting Services Agreement between Longeveron Inc. and Stephen Willard dated January 29, 2026, filed herewith

Exhibit Number	Description of Exhibit
10.6#	Consulting Services Agreement between Longeveron Inc. and J. Nathaniel Powell dated February 23, 2026, filed herewith
10.7†	Lease Agreement, dated October 6, 2015 by and between Wexford Miami, LLC and Longeveron LLC, incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.8†	Grant Agreement, dated October 1, 2020 by and between the Maryland Stem Cell Research Commission, acting by and through the Maryland Technology Development Corporation, and Longeveron LLC, incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.9#	2017 Longeveron LLC Incentive Plan, dated July 18, 2017, incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.10#	Longeveron Inc. 2021 Incentive Award Plan, incorporated by reference to Exhibit 10.13 on Registrant's Registration Statement No. 333-252234 filed February 3, 2021
10.10.1#	Amended and Restated Longeveron Inc. 2021 Incentive Award Plan, incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement, filed April 28, 2023
10.10.2#	Second Amended and Restated Longeveron Inc. 2021 Incentive Award Plan, incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement filed on May 20, 2024
10.10.3#	Third Amended and Restated Longeveron Inc. 2021 Incentive Award Plan, incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 Filed June 20, 2025
10.11	Form of Indemnification Agreement for Officers and Directors, incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement No. 333-252234 filed February 3, 2021
10.12^	Form of Securities Purchase Agreement, incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed December 3, 2021
10.13^	Form of Registration Rights Agreement, incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed December 3, 2021
10.14^	Form of Securities Purchase Agreement, dated October 11, 2023, by and between the Company and the Purchaser signatory thereto, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed October 13, 2023
10.15^	Form of Securities Purchase Agreement, dated December 20, 2023, by and between the Company and the Purchaser signatory thereto, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 22, 2023
10.16^	Form of Securities Purchase Agreement, dated April 8, 2024, by and between the Registrant and the Purchasers signatory thereto, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed April 11, 2024
10.17	Form of Warrant Amendment Agreement, dated April 8, 2024, by and between the Registrant and the Holder, incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed April 11, 2024
10.18^	Form of Inducement Letter Agreement, dated April 16, 2024, by and between the Registrant and each Holder, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed April 18, 2024
10.19^	Form of Inducement Letter Agreement, dated June 17, 2024, by and between the Registrant and each Holder, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 18, 2024
10.20^	Form of Securities Purchase Agreement, dated July 18, 2024, by and between the Company and the Purchasers signatory thereto, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 19, 2024
10.21^	Form of Securities Purchase Agreement, dated August 8, 2025, by and between the Company and the purchasers party thereto, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed August 11, 2025
10.22	ATM Agreement, dated September 19, 2025 by and between the Company and H.C. Wainwright & Co., LLC, incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed September 19, 2025
10.23^	Form of Purchase Agreement, dated March 10, 2026, by and between the Company and each Investor identified on Exhibit A thereto, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 12, 2026

Exhibit Number	Description of Exhibit
10.24	Form of Registration Rights Agreement, incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed March 12, 2026
10.25#	Employment Agreement between Longeveron Inc. and Wa'el Hashad, incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed February 28, 2023.
10.25.1#	Employment Agreement between Longeveron Inc. and Wa'el Hashad, dated February 21, 2023, as amended January 17, 2025, incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed on February 28, 2025.
10.25.2#	Separation Agreement and General Release, effective September 9, 2025, between Longeveron Inc. and Wa'el Hashad, filed herewith.
10.26#	Letter Agreement between Longeveron Inc. and Paul Lehr dated March 14, 2024, filed herewith.
10.27#	Letter Agreement between Longeveron Inc. and Lisa Locklear, dated July 14, 2023, incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed on February 27, 2024
10.28#	Letter Agreement between Longeveron Inc. and Nataliya Agafonova, M.D. dated June 21, 2023, incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K filed on February 27, 2024
10.29#	Letter Agreement between Longeveron Inc. and Devin Blass dated October 17, 2024, filed herewith.
10.30#	Letter Agreement between Longeveron Inc. and J. Nathaniel Powell dated September 3, 2025, filed herewith
10.31#	Letter Agreement between Longeveron Inc. and Stephen Willard dated February 11, 2026, incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed on February 13, 2026
16.1	Letter to Securities and Exchange Commission from Marcum LLP dated March 14, 2025, incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K filed March 14, 2025
19.1	Longeveron Inc. Statement of Policy on Insider Trading, incorporated by reference to the Registrant's Annual Report on Form 10-K filed on February 28, 2025
21.1	Subsidiaries of the Registrant, incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
23.1	Consent of CBIZ CPAs P.C., Independent Registered Public Accounting Firm
23.2	Consent of Marcum LLP, former Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith
31.2	Certification of the Chief Financial Officer pursuant SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, furnished herewith
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, furnished herewith
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation, incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K filed on February 27, 2024.
101.INS	Inline XBRL Instance Document — the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL Document
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents
104	Inline Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv). This information is not material and is of the type that the registrant treats as private or confidential.

^ Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish copies of any of the omitted schedules upon request by the SEC.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

LONGEVERON INC

March 17, 2026

By: /s/ Stephen H. Willard
Stephen H. Willard
Chief Executive Officer
(principal executive officer)

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

Signature	Title	Date
/s/ Stephen H. Willard Stephen H. Willard	Chief Executive Officer (principal executive officer)	March 17, 2026
/s/ Lisa A. Locklear Lisa A. Locklear	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 17, 2026
/s/ Joshua M. Hare Joshua M. Hare	Director	March 17, 2026
/s/ Rock Soffer Rock Soffer	Director	March 17, 2026
/s/ Roger Hajjar Roger Hajjar	Director	March 17, 2026
/s/ George Paletta, Jr. George Paletta, Jr.	Director	March 17, 2026
/s/ Ursula Ungaro Ursula Ungaro	Director	March 17, 2026

LONGEVERON, INC
FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Longeveron Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Longeveron Inc. (the "Company") as of December 31, 2025, the related statements of operations, stockholders' equity and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph — Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations over the next twelve months. These conditions 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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2022 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Hartford, CT
March 17, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Longeveron Inc.

Opinion on the Financial Statements

We have audited, before the effects of the adjustments to retrospectively apply the change in accounting described in Note 11, the accompanying balance sheet of Longeveron Inc. (the "Company") as of December 31, 2024, the related statements of operations, stockholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements" and the 2024 financial statements before the effects of the adjustments discussed in Note 11 are not presented herein). In our opinion, based on our audit, the 2024 financial statements, before the effects of the adjustments to retrospectively apply the change in accounting described in Note 11, present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the adjustments to retrospectively apply the change in accounting described in Note 11 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by CBIZ CPAs.

Explanatory Paragraph — Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations over the next twelve months. These conditions 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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We served as the Company's auditor from 2022 through 2025.

Hartford, CT
February 28, 2025

Longeveron Inc.
Balance Sheets
(In thousands, except share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 4,661	$ 19,232
Prepaid expenses and other current assets	686	308
Accounts and grants receivable	104	84
Total current assets	5,451	19,624
Property and equipment, net	1,836	2,449
Intangible assets, net	2,285	2,401
Operating lease asset	513	882
Other assets	176	202
Total assets	$ 10,261	$ 25,558
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 423	$ 99
Accrued expenses	2,969	1,820
Current portion of operating lease liability	655	623
Deferred revenue	40	40
Total current liabilities	4,087	2,582
Long-term liabilities:		
Long-term portion of operating lease liability	169	824
Other liabilities	330	265
Total long-term liabilities	499	1,089
Total liabilities	4,586	3,671
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, $0.001 par value per share, 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Class A common stock, $0.001 par value per share, 84,295,000 shares authorized, 21,445,336 shares issued and outstanding at December 31, 2025; 13,407,441 issued and outstanding at December 31, 2024	21	13
Class B common stock, $0.001 par value per share, 15,705,000 shares authorized, 1,484,005 shares issued and outstanding at December 31, 2025 and December 31, 2024	1	1
Additional paid-in capital	137,964	131,480
Accumulated deficit	(132,311)	(109,607)
Total stockholders' equity	5,675	21,887
Total liabilities and stockholders' equity	$ 10,261	$ 25,558

See accompanying Notes to the Financial Statements.

Longeveron Inc.
Statements of Operations
(In thousands, except per share data)

	Year Ended December 31,	
	2025	**2024**
Revenues		
Clinical trial revenue	$ 954	$ 1,402
Contract manufacturing lease revenue	23	503
Contract manufacturing revenue	222	487
Total revenues	1,199	2,392
Cost of revenues	396	508
Gross profit	803	1,884
Operating expenses		
General and administrative	12,049	10,269
Research and development	12,041	8,137
Total operating expenses	24,090	18,406
Loss from operations	(23,287)	(16,522)
Other income and (expense)		
Loss on disposal of assets	(97)	—
Other income	680	549
Total other income, net	583	549
Net loss	$ (22,704)	$ (15,973)
Deemed dividend – warrant inducement offers	—	(8,650)
Net loss attributable to common stockholders	$ (22,704)	$ (24,623)
Basic and diluted net loss per share	$ (1.29)	$ (2.62)
Basic and diluted weighted average common shares outstanding	17,576,551	9,411,164

See accompanying Notes to the Financial Statements.

Longeveron Inc.
Statements of Stockholders' Equity
(In thousands, except share amounts)

	Class A Common Stock		Class B Common Stock		Subscription Receivable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount	Number	Amount				
Balance at January 1, 2024	1,025,183	$ 1	1,485,560	$ 1	$ (100)	$ 91,823	$ (84,984)	$ 6,741
Conversion of Class B common stock for Class A common stock	1,555		(1,555)	—	—	—	—	—
Class A common stock, issued for RSUs vested	566,904	—	—	—	—	—	—	—
Class A common stock, held for taxes on RSUs vested	(142,306)	—	—	—	—	(349)		(349)
Class A common stock, issued for PSUs vested	8,020	—	—	—	—	—	—	—
Class A common stock, held for taxes on PSUs vested	(3,286)	—	—	—	—	(17)	—	(17)
Collection of stock subscription receivable	—	—	—	—	100	—	—	100
Equity-based compensation	—	—	—	—	—	2,328	—	2,328
Class A common stock issued in public offering, net of issuance cost of $2,064	4,448,792	4	—	—	—	12,862	—	12,866
Class A common stock issue for warrants exercised, net of issuance cost of $1,855	7,435,609	8	—	—	—	16,183	—	16,191
Deemed dividend – warrant inducement offers	—	—	—	—	—	8,650	(8,650)	—
Reverse stock split rounding adjustment	66,970	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(15,973)	(15,973)
Balance at December 31, 2024	13,407,441	$ 13	1,484,005	$ 1	$ —	$ 131,480	$ (109,607)	$ 21,887
Class A common stock, issued for RSUs vested	655,922	—	—	—	—	—	—	—
Class A common stock, held for taxes on RSUs vested	(260,007)	—	—	—	—	(311)	—	(311)
Equity-based compensation	—	—	—	—	—	1,677	—	1,677
Class A common stock issued in public offering, net of issuance cost of $1,198	7,641,980	8	—	—	—	4,972	—	4,980
Cash-for-Equity program	—	—	—	—	—	146	—	146
Net loss	—	—	—	—	—	—	(22,704)	(22,704)
Balance at December 31, 2025	21,445,336	$ 21	1,484,005	$ 1	$ —	$ 137,964	$ (132,311)	$ 5,675

See accompanying Notes to the Financial Statements.

Longeveron Inc.
Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (22,704)	$ (15,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,226	958
Interest earned on marketable securities	—	60
Equity-based compensation	1,677	2,328
Loss on disposal of assets	97	—
Changes in operating assets and liabilities:		
Accounts and grants receivable	(20)	27
Prepaid expenses and other current assets	(378)	68
Other assets	25	(9)
Accounts payable	325	(540)
Deferred revenue	—	(466)
Accrued expenses	1,295	(332)
Operating lease asset and liability	(254)	(254)
Other liabilities	66	265
Net cash used in operating activities	(18,645)	(13,868)
Cash flows from investing activities:		
Proceeds from the sale of marketable securities	—	352
Acquisition of property and equipment	(245)	(655)
Acquisition of intangible assets	(350)	(337)
Net cash used in investing activities	(595)	(640)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of issuance cost	4,980	12,866
Proceeds from warrants exercised, net of issuance cost	—	16,191
Proceeds from stock subscription receivable	—	100
Payments for taxes on RSUs vested and PSUs vested	(311)	(366)
Net cash provided by financing activities	4,669	28,791
Change in cash and cash equivalents	(14,571)	14,283
Cash and cash equivalents at beginning of period	19,232	4,949
Cash and cash equivalents at end of period	$ 4,661	$ 19,232
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Vesting of RSUs into Class A Common Stock	$ (797)	$ (1,109)
Offering costs in accounts payable and accrued expenses	$ 28	$ —
Deemed dividend – warrant inducement offers	$ —	$ 8,650

See accompanying Notes to the Financial Statements.

1. Nature of Business, Basis of Presentation, and Liquidity

Nature of Business:

Longeveron LLC was formed as a Delaware limited liability company on October 9, 2014 and authorized to transact business in Florida on December 15, 2014. On February 12, 2021, Longeveron LLC converted its corporate form (the "Corporate Conversion") from a Delaware limited liability company (Longeveron, LLC) to a Delaware corporation, Longeveron Inc. (the "Company," "Registrant," "Longeveron,", "we," "us," or "our"). The Company is a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. The Company operates out of its leased facilities in Miami, Florida.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on licenses, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing to fund operations. Investigational product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical studies and clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting capabilities.

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

Going Concern and Liquidity:

Since inception, the Company has primarily been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the U.S. Food and Drug Administration ("FDA"), and has only generated revenues from grants, The Bahamas Registry Trials and contract manufacturing. The Company has not yet achieved profitable operations or generated positive cash flows from operations. The Company intends to continue its efforts to raise additional equity financing, develop its intellectual property, and secure regulatory approvals to commercialize its products. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital, its research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of the Company's products. These financial statements do not include adjustments that might result from the outcome of these uncertainties.

The Company has incurred recurring losses from operations since its inception, including a net loss of $22.7 million and $16.0 million for the years ended December 31, 2025 and 2024, respectively. In addition, as of December 31, 2025, the Company had an accumulated deficit of $132.3 million. The Company expects to continue to generate operating losses for the foreseeable future.

As of December 31, 2025, the Company had cash and cash equivalents of $4.7 million. As a result of the recently completed private placement financing referenced in Note 14, Subsequent Events, and based on current operating plans, the Company expects that its cash and cash equivalents as of December 31, 2025 plus the $15.9 million in gross proceeds from the private placement will fund operations into the fourth quarter of 2026. The Company also has access to an At-The-Market (ATM) equity financing vehicle for the sale of up to $10.7 million aggregate market value of shares of the Company's Class A common stock. Following a successful Type C meeting with the FDA in August 2024 with respect to the HLHS regulatory pathway, the Company has begun ramping up BLA enabling activities, with a focus on clinical spend supporting HLHS study completion and delivering top-line results.

1. Nature of Business, Basis of Presentation, and Liquidity (cont.)

The Company currently anticipates a potential BLA filing with the FDA in 2027 and plans to seek a commercialization partner if the current ELPIS II trial in HLHS is successful. Additionally, following a positive Type B meeting with the FDA in March 2025 with respect to the AD regulatory pathway, the Company is focused on seeking partnership opportunities and/or non-dilutive funding for the AD program, including a proposed single, pivotal seamless adaptive Phase 2/3 clinical trial. The Company expects that its current operating plan will require increased spending and additional capital investments to support these initiatives, and intends to seek additional financing through capital raises, non-dilutive funding options, and commercial partnering across all indications to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into. There can be no assurance the Company will be able to attain future financing at terms favorable to the Company or at all. In the event the Company is unable to attain the financing needed, it will need to materially revise its current operational plan. The Company may need to further adjust its current and future spending levels, if needed, based on the level of cash available.

The Company has prepared a cash flow forecast which indicates that it does not have sufficient cash to meet its minimum expenditure commitments for one year from the date these financial statements are available to be issued and therefore needs to raise additional funds to continue as a going concern. As a result, there is substantial doubt about the Company's ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation:

The financial statements of the Company were prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"), as well as the applicable rules and regulations of the Securities and Exchange Commission.

Reverse Stock Split:

On March 26, 2024, the Company effected a reverse stock split of the outstanding shares of its Class A common stock and Class B common stock on a one-for-10 (1:10) basis (the "Reverse Stock Split"). The Reverse Stock Split became effective at 11:59 p.m. Eastern Time on March 26, 2024 via a certificate of amendment to the Company's Certificate of Incorporation filed with the Secretary of State of the State of Delaware. At the effective time of the Reverse Stock Split, every 10 shares of the Company's Class A common stock and Class B common stock, whether issued and outstanding or held by the Company as treasury stock, were automatically combined and converted (without any further act) into one fully paid and nonassessable share of Class A common stock or Class B common stock, respectively, subject to rounding up of fractional shares to the nearest whole number of shares resulting from the Reverse Stock Split without any change in the par value per share. All share, per share, option, warrant, equity award, and other derivative security numbers and exercise prices appearing in this Annual Report on Form 10-K and the accompanying financial statements have been adjusted to give effect to the Reverse Stock Split for all prior periods presented. However, the Company's annual, other periodic, and current reports, and all other information and documents incorporated by reference into this Annual Report on Form 10-K that were filed prior to March 19, 2024, do not give effect to the Reverse Stock Split.

Use of Estimates:

The presentation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. Summary of Significant Accounting Policies (cont.)

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its consolidated financial statements or disclosures.

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This standard establishes incremental disaggregation of income tax disclosures pertaining to the effective tax rate reconciliation and income taxes paid. The amendments in this update are required to be applied on a prospective basis with the option to apply it retrospectively. This standard is effective for annual reporting for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company adopted this standard and applied the disclosure requirements on a retrospective basis effective for the year ended December 31, 2025. The adoption did not have a material impact on the Company's consolidated financial position or results of operations. Refer to *Note 11, Income Taxes*, for updated income tax disclosure.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement (Subtopic 220-40): Reporting Comprehensive Income — Expense Disaggregation Disclosures. This standard requires disclosure in the notes to the financial statements, at each interim and annual reporting period, of specified information about certain costs and expense including purchases of inventory, employee compensation, depreciation and intangible asset amortization included in each relevant expense caption. This standard also requires a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated, as well as disclosure of the total amount of selling expenses, and, in annual reporting periods, an entity's definition of selling expenses. This standard is effective for annual reporting for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the potential impact that this new standard will have on its consolidated financial statements and related disclosures and expects to apply this standard prospectively upon adoption.

In September 2025, the FASB issued ASU No. 2025-06, Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Targeted Improvements to the accounting for Internal-Use Software. This standard modernizes the accounting for software costs, including updating guidance on the recognition and measurement of costs incurred in connection with development and implementation activities related to internal-use software. This standard is effective for annual reporting for fiscal periods beginning after December 15, 2027, and interim periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the potential impact that this new standard will have on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU No. 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. This standard refines and expands the existing scope exceptions that exclude certain contracts, including certain R&D funding arrangements, from derivative accounting, and clarifies the accounting for share-based noncash consideration received from a customer. This standard is effective for annual reporting for fiscal years beginning after December 15, 2026, and interim periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the potential impact that this new standard will have on its consolidated financial statements and related disclosures.

Cash and Cash Equivalents:

The Company considers cash to consist of cash and cash equivalents and temporary investments having an original maturity of 90 days or less that are readily convertible into cash.

2. Summary of Significant Accounting Policies (cont.)

Fair Value Measurement:

The Company measures cash equivalents at fair value. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value is defined as the price we would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value.

- *Level 1* — Unadjusted quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities.
- *Level 2* — Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.
- *Level 3* — Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

Money market funds are highly liquid investments and are classified as Level 1. The pricing information for these assets is readily available and can be independently validated as of the measurement date.

Accounts and Grants Receivable:

Accounts and grants receivable include amounts due from customers, granting institutions and others. The amounts as of December 31, 2025 and 2024 are deemed to be collectible and no amount has been recognized for credit losses. In addition, for the clinical trial revenue, most participants pay in advance of treatment. Advanced grant funds and prepayments for the clinical trial revenue are recorded to deferred revenue. Advance contract manufacturing payments are recorded to deferred revenue.

Accounts and grants receivable by source (in thousands):

	December 31,	
	2025	2024
Accounts receivable	$ 104	$ 25
National Institutes of Health – Grant	—	59
Total	$ 104	$ 84

Deferred Offering Costs:

The Company recorded certain legal, professional and other third-party fees that were directly associated with in-process equity financings as deferred offering costs until the applicable equity financing was consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity as a reduction of proceeds generated as a result of the offering.

Property and Equipment:

Property and equipment, including improvements that extend useful lives of related assets, are recorded at cost, while maintenance and repairs are charged to operations as incurred. Depreciation is calculated using the straight-line method based on the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the estimated useful life of the asset or the original term of the lease. Depreciation expense is recorded in the research and development line of the Statement of Operations as the assets are primarily related to the Company's clinical programs.

2. Summary of Significant Accounting Policies (cont.)

Intangible Assets:

Intangible assets include payments on license agreements with the Company's co-founder and Chief Scientific Officer ("CSO") and the University of Miami ("UM") (see Note 9) and legal costs incurred related to patents and trademarks. License agreements have been recorded at the value of cash consideration, common stock and membership units transferred to the respective parties when acquired.

Payments for license agreements are amortized using the straight-line method over the estimated term of the agreements, which range from 5-20 years. Patents are amortized over their estimated useful life, once issued. The Company considers trademarks to have an indefinite useful life and evaluates them for impairment on an annual basis. Amortization expense is recorded in the research and development line of the statements of operations as the assets are primarily related to the Company's clinical programs.

Impairment of Long-Lived Assets:

The Company evaluates long-lived assets for impairment, including property and equipment and intangible assets, when events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Upon the occurrence of a triggering event, the asset is reviewed to assess whether the estimated undiscounted cash flows expected from the use of the asset plus the residual value from the ultimate disposal exceeds the carrying value of the asset. If the carrying value exceeds the estimated fair value, the asset is written down to the estimated fair value. Any resulting impairment loss is reflected on the statements of operations. Upon evaluation, management determined that there was no impairment of long-lived assets during the years ended December 31, 2025 and 2024.

Deferred Revenue:

The unearned portion of advanced grant funds, contract manufacturing revenues, and prepayments for clinical trial revenue, which will be recognized as revenue when the Company meets the respective performance obligations, has been presented as deferred revenue in the balance sheets.

Warrants

The Company determines the accounting classification of warrants that are issued, 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, ("ASC 480-10"), and then in accordance with ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity ("ASC 815-40"). Under ASC 480-10, warrants are considered liability-classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If the 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, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common shares and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability-classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other income (expense), net in the statements of operations. Equity-classified warrants are accounted for at consideration received on the issuance date with no changes in fair value recognized after the issuance date. As of December 31, 2025 and 2024, respectively, all of the Company's outstanding warrants are equity-classified warrants. (See Note 7).

2. Summary of Significant Accounting Policies (cont.)

Revenue Recognition:

The Company recognizes revenue when performance obligations related to respective revenue streams are met.

For clinical trial revenue, the Company considers the performance obligation met when the participant has received the treatment. The Company usually receives prepayment for these services or receives payment at the time the treatment is provided, and there are no remaining performance obligations or variable consideration once the participant received the treatment.

For contract manufacturing revenue, the Company considers the performance obligation met when the contractual obligation and/or statement of work has been satisfied. Additionally, the Company's contract manufacturing agreements include a lease component, under which customers pay a fixed monthly fee per suite to reserve and maintain a dedicated manufacturing suite with one production line. Customers may also secure additional suites based on capacity needs, which are billed at a fixed fee per suite per month. Furthermore, customers pay the Company a fixed fee per month for storage of in-process samples, vialed harvests for training, and in-process samples for product lots. As these arrangements grant customers the right to control the use of an identified space, the Company classifies the suite reservation fees and storage fees as lease revenue in accordance with ASC 842 Leases. Payment terms may vary depending on specific contract terms. In 2025, the Company derived 100% of its contract manufacturing revenue from a single customer, resulting in a significant concentration of revenue risk. Activities with this customer have substantially decreased during 2025, and no additional manufacturing or development work is currently planned. The Company does not anticipate significant future manufacturing revenue with this customer.

Revenue by source (in thousands):

	Year Ended December 31,	
	2025	**2024**
Clinical trial revenue	$ 954	$ 1,402
Contract manufacturing lease revenue	23	503
Contract manufacturing revenue	222	487
Total	$ 1,199	$ 2,392

The Company records cost of revenues based on expenses directly related to revenue. For the Clinical trial revenue directly related expenses for that program are expensed as incurred. These expenses are similar to those described under "Research and development expense" below. For the contract manufacturing, the Company records costs incurred under the contract as cost of revenues.

Research and Development Expense:

Research and development costs are charged to expense when incurred in accordance with ASC 730 *Research and Development*. ASC 730 addresses the proper accounting and reporting for research and development costs. It identifies: 1) those activities that should be identified as research and development; 2) the elements of costs that should be identified with research and development activities, and the accounting for these costs; and 3) the financial statement disclosures related to them. Research and development costs include costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, property and equipment depreciation and allocation of various corporate costs. The Company accrues for costs incurred by external service providers, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, patient enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

2. Summary of Significant Accounting Policies (cont.)

Concentrations of Credit Risk:

Financial instruments which potentially subject the Company to credit risk consist principally of cash and cash equivalents, marketable securities, and accounts and grants receivable. Cash and cash equivalents are held in U.S. financial institutions. At times, the Company may maintain balances in excess of the federally insured amounts.

Income Taxes:

The Company's tax provision consists of taxes currently payable or receivable, plus any change during the period in deferred tax assets and liabilities. The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. In addition, a valuation allowance is established to reduce any deferred tax asset for which it is determined that it is more likely than not that some portion of the deferred tax asset will not be realized. The Company's tax provision was $0 for the years ended December 31, 2025 and 2024 due to net operating losses. The Company has not recorded any tax benefit for the net operating losses incurred due to the uncertainty of realizing a benefit in the future.

The Company recognizes the tax benefits from uncertain tax positions that the Company has taken or expects to take on a tax return. In the unlikely event an uncertain tax position exists in which the Company could incur income taxes, the Company would evaluate whether there is a probability that the uncertain tax position taken would be sustained upon examination by a taxing authority. Reserves for uncertain tax positions would then be recorded if the Company determined it is probable that either a position would not be sustained upon examination or a payment would have to be made to a taxing authority and the amount was reasonably estimable. As of December 31, 2025 and 2024, the Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authority. It is the Company's policy to expense any interest and penalties associated with its tax obligations when they are probable and estimable.

Equity-Based Compensation:

The Company accounts for equity-based compensation expense by the measurement and recognition of compensation expense for equity-based awards based on estimated fair values on the date of grant. The fair value of the options is estimated at the date of the grant using the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model requires the input of highly subjective assumptions, the most significant of which are the expected share price volatility, the expected life of the option award, the risk-free rate of return, and dividends during the expected term. Because the option-pricing model is sensitive to changes in the input assumptions, different determinations of the required inputs may result in different fair value estimates of the options.

Neither the Company's stock options nor its restricted stock units ("RSUs") trade on an active market. Volatility is a measure of the amount by which a financial variable, such as a stock price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. Given the Company's limited historical data, the Company utilizes the average historical volatility of similar publicly traded companies that are in the same industry. The risk-free interest rate is the average U.S. treasury rate (having a term that most closely approximates the expected life of the option) for the period in which the option was granted. The expected life is the period of time that the options granted are expected to remain outstanding. Options granted have a maximum term of ten years. The Company had insufficient historical data to utilize in determining its expected life assumptions and, therefore, uses the simplified method for determining expected life.

3. Marketable Securities

The following is summary of marketable securities that the Company measures at fair value (in thousands):

	Fair Value at December 31, 2025			
	Level 1	Level 2	Level 3	Total
Money market funds[(1)]	$ 3,500	$ —	$ —	$ 3,500
Accrued income	11	—	—	11
Total money market funds	$ 3,511	$ —	$ —	$ 3,511

(1) Money market funds are included in cash and cash equivalents in the balance sheets.

	Fair Value at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Money market funds[(1)]	$ 6,877	$ —	$ —	$ 6,877
Accrued income	25	—	—	25
Total marketable securities	$ 6,902	$ —	$ —	$ 6,902

(1) Money market funds are included in cash and cash equivalents in the balance sheets.

As of December 31, 2025 and 2024, the Company reported accrued interest receivable related to money market funds of less than $0.1 million. These amounts are recorded in other assets on the Balance Sheets and are not included in the carrying value of the money market funds.

4. Property and Equipment, Net

Major components of property and equipment are as follows (in thousands):

	Useful Lives	December 31, 2025	December 31, 2024
Leasehold improvements	10 years	$ 4,410	$ 4,402
Furniture/Lab equipment	7 years	3,114	3,063
Computer equipment	5 years	97	120
Software/Website	3 years	38	38
Total property and equipment		7,659	7,623
Less accumulated depreciation and amortization		5,823	5,174
Property and equipment, net		$ 1,836	$ 2,449

Depreciation and amortization expense amounted to approximately $0.8 and $0.7 million for the years ended December 31, 2025 and 2024, respectively. During the year ended December 31, 2025, the Company wrote off approximately $0.2 million in laboratory and computer equipment resulting in approximately $0.1 million non-cash loss.

5. Intangible Assets, Net

Major components of intangible assets as of December 31, 2025 are as follows (in thousands):

	Useful Lives	Cost	Accumulated Amortization	Total
License agreements	20 years	$ 2,043	$ (1,356)	$ 687
Patent costs	20 years	1,610	(242)	1,368
Trademark costs		230	—	230
Total		$ 3,883	$ (1,598)	$ 2,285

5. Intangible Assets, Net (cont.)

Major components of intangible assets as of December 31, 2024, are as follows (in thousands):

	Useful Lives	Cost	Accumulated Amortization	Total
License agreements	20 years	$ 2,043	$ (1,132)	$ 911
Patent costs	20 years	1,273	—	1,273
Trademark costs		217	—	217
Total		$ 3,533	$ (1,132)	$ 2,401

Amortization expense related to intangible assets amounted to approximately $0.4 and $0.2 million for the years ended December 31, 2025 and 2024, respectively. There were no impairments of intangibles nor write-offs of intangibles in 2025 or 2024.

Future amortization expense for intangible assets as of December 31, 2025 is approximately as follows (in thousands):

Year Ending December 31,	Amount
2026	$ 166
2027	126
2028	126
2029	126
2030	126
Thereafter	1,385
Total	$ 2,055

6. Leases

The Company has an operating lease for office and laboratory space under an agreement which provides the right to use the underlying asset and requires lease payments during the lease term. The Company recorded a right-of-use operating lease asset and a lease liability related to its operating lease (there are no finance leases). The Company's lease expires in April 2027. The lease arrangement contains renewal provisions, exercisable at the Company's option. The probability of renewal is not reasonably certain and therefore not included in the right-of-use asset and lease liability. The Company's lease agreement does not contain any material residual value guarantees or material restrictive covenants.

Operating lease cost was $0.8 million for the years ended December 31, 2025 and 2024. Operating lease costs included in cost of revenues for the years ended December 31, 2025 and 2024 was immaterial.

Information related to leases (in thousands):

	Year Ended December 31,	
Operating Leases	**2025**	**2024**
Operating cash flow information:		
Operating lease cost	$ 799	$ 811
Operating lease – cash flow	$ 1,053	$ 1,065
Weighted-average remaining lease term (years)	1.3	2.3
Weighted-average discount rate (percentage)	5.0%	5.0%

6. Leases (cont.)

Future minimum payments under the operating leases as of December 31, 2025 are as follows (in thousands):

Year Ending December 31,	Amount
2026	$ 682
2027	170
Total	$ 852
Less interest (5% discount rate)	(28)
Total lease liability	$ 824
Reported as:	
Current portion of operating lease liability	$ 655
Long-term portion of lease liability	169
Total lease liability	$ 824

7. Stockholders' Equity

Class A and Class B Common Stock

Holders of Class A common stock generally have rights identical to holders of Class B common stock, except that holders of Class A common stock are entitled to one vote per share and holders of Class B common stock are entitled to five (5) votes per share. The holders of Class B common stock may convert each share of Class B common stock into one share of Class A common stock at any time at the holder's option. Class B common stock is not publicly tradable.

During the year ended December 31, 2025, stockholders converted no shares of Class B common stock into shares of Class A common stock. During the year ended December 31, 2024, stockholders exchanged 1,555 shares of Class B common stock for 1,555 shares of Class A common stock.

Warrants

Summary of Warrants Outstanding

As of December 31, 2025, warrants exercisable for an aggregate of up to 21,920,318 shares of the Company's Class A common stock remain outstanding. This includes:

- warrants exercisable for up to 5,536 shares of Class A common stock at an exercise price of $120.00 per share, which expired on February 12, 2026.
- warrants exercisable for up to 4,679 shares of Class A common stock at an exercise price of $175.00 per share, which expire December 1, 2026.
- warrants exercisable for up to 16,971 shares of Class A common stock at an exercise price of $20.625 per share, which expire October 11, 2028.
- warrants exercisable for up to 135,531 shares of Class A common stock at an exercise price of $16.20 per share, which expire June 22, 2029.
- warrants exercisable for up to 9,489 shares of Class A common stock at an exercise price of $21.813 per share, which expire December 20, 2028.
- warrants exercisable for up to 297,872 shares of Class A common stock at an exercise price of $2.35 per share, which expire April 10, 2029.

7. Stockholders' Equity (cont.)

- warrants exercisable for up to 154,894 shares of Class A common stock at an exercise price of $2.9375 per share, which expire April 8, 2029.
- warrants exercisable for up to 2,349,744 shares of Class A common stock at an exercise price of $2.35 per share, which expire April 18, 2029.
- warrants exercisable for up to 167,982 shares of Class A common stock at an exercise price of $3.25 per share, which expire April 18, 2029.
- warrants exercisable for up to 49,130 shares of Class A common stock at an exercise price of $2.9375 per share, which expire June 18, 2026.
- warrants exercisable for up to 926,596 shares of Class A common stock at an exercise price of $2.50 per share, which expire June 18, 2026.
- warrants exercisable for up to 118,852 shares of Class A common stock at an exercise price of $3.25 per share, which expire June 18, 2026.
- warrants exercisable for up to 10,500 shares of Class A common stock at an exercise price of $3.125 per share, which expire July 17, 2026.
- warrants exercisable for up to 162,344 shares of Class A common stock at an exercise price of $3.125 per share, which expire July 24, 2026.
- warrants exercisable for up to 2,236,026 shares of Class A common stock at an exercise price of $3.90 per share, which expire July 20, 2026.
- warrants exercisable for up to 156,522 shares of Class A common stock at an exercise price of $5.0313 per share, which expire July 20, 2026.
- warrants exercisable for up to 14,705,885 shares of Class A common stock at an exercise price of $0.85 per share, which expire August 11, 2027.
- warrants exercisable for up to 411,765 shares of Class A common stock at an exercise price of $1.0625 per share, which expire August 11, 2027.

8. Equity Incentive Plan

RSUs

As part of the Company's IPO, the Company adopted and approved the 2021 Incentive Award Plan, which has been subsequently amended and restated three times (as accordingly amended and restated, the "2021 Incentive Plan"). Under the 2021 Incentive Plan, the Company may grant cash and equity incentive awards to employees and eligible service providers in order to attract, motivate and retain the talent for which the Company competes.

RSUs are taxable upon vesting based on the market value on the date of vesting. The Company is required to make mandatory tax withholding for the payment and satisfaction of income tax, social security tax, payroll tax, or payment on account of other tax related to withholding obligations that arise by reason of vesting of an RSU. The taxable income is calculated by multiplying the number of vested RSUs for each individual by the closing share price as of the vesting date and a tax liability is calculated based on each individual's tax bracket. During the year ended December 31, 2025, a total of 655,922 RSUs vested for Class A common stock shares. Of that amount, the Company withheld 260,007 Class A common stock shares to satisfy employee tax liabilities. During the year ended December 31, 2024, a total of 566,904 RSUs vested for Class A common stock shares. Of that amount, the Company withheld 142,306 Class A common stock shares to satisfy employee tax liabilities. The shares withheld are available

8. Equity Incentive Plan (cont.)

for reissuance pursuant to the Company's 2021 Incentive Plan. Each RSU grant made during 2025 and 2024 is expensed ratably over its respective vesting period, with prorated adjustments made as needed to align with grant dates and the applicable service periods.

As of December 31, 2025 and 2024, the Company had 1,209,738 and 806,001, respectively RSUs outstanding (unvested).

RSU activity for the year ended December 31, 2025 was as follows:

	Number of RSUs
Outstanding (unvested) at December 31, 2024	806,001
RSUs granted	1,409,193
RSUs vested	(655,922)
RSU expired/forfeited	(349,534)
Outstanding (unvested) at December 31, 2025	1,209,738

Stock Options

Stock options may be granted under the 2021 Incentive Plan. The exercise price of options is equal to the fair market value of the Company's Class A common stock as of the grant date. Options historically granted have generally become exercisable over three or four years and expire ten years from the date of grant.

The fair value of the options issued in 2025 were estimated using the Black-Scholes option-pricing model and had the following assumptions: a dividend yield of 0%; an expected life ranging from 5 to 7 years; volatility ranging from 76% to 82%; and risk-free interest rate based on the grant date ranging from 3.84 to 4.26%. The fair value of the options issued during 2024 were estimated using the Black-Scholes option-pricing model and had the following assumptions: a dividend yield of 0%; an expected life of 10 years; volatility ranging from 79%-95%; and risk-free interest rate based on the grant date ranging from 3.79% to 4.52%. Each option grant is being expensed ratably over the option vesting periods, with prorated adjustments made as needed to align with grant dates and applicable service period.

As of December 31, 2025, the Company has recorded issued and outstanding options to purchase a total of 658,187 shares of Class A common stock pursuant to the 2021 Incentive Plan, at a weighted average exercise price of $3.18 per share. Also, as of December 31, 2024, the Company has recorded issued and outstanding options to purchase a total of 121,186 shares of Class A common stock pursuant to the 2021 Incentive Plan, at a weighted average exercise price of $15.09 per share.

For the year ended December 31, 2025:

	Number of Stock Options
Stock options vested (based on ratable vesting)	370,394
Stock options unvested	287,793
Total stock options outstanding at December 31, 2025	658,187

For the year ended December 31, 2024:

	Number of Stock Options
Stock options vested (based on ratable vesting)	31,713
Stock options unvested	89,473
Total stock options outstanding at December 31, 2024	121,186

8. Equity Incentive Plan (cont.)

Stock Option activity for the year ended December 31, 2025 was as follows:

	Number of Stock Options	Weighted Average Exercise Price
Outstanding at December 31, 2024	121,186	$ 15.09
Options granted	637,601	1.42
Options exercised	—	—
Options expired/forfeited	(100,600)	13.44
Outstanding at December 31, 2025	658,187	$ 3.18

For the years ended December 31, 2025 and 2024, the equity-based compensation expense amounted to approximately $1.7 million and $2.3 million, respectively, which is included in the research and development and general and administrative expenses in the statements of operations for the years ended December 31, 2025 and 2024.

As of December 31, 2025, the remaining unrecognized RSUs compensation of approximately $1.5 million will be recognized over approximately 1.9 years. The remaining unrecognized stock options compensation of approximately $0.3 million will be recognized over approximately 2.2 years.

9. Commitments and Contingencies

Master Services and Clinical Studies Agreements:

During 2024, the Company terminated its active master services agreements with third parties that were previously engaged to conduct its clinical trials and manage clinical research programs and clinical development services in Japan. This termination was due to the Company's decision in April 2024 to discontinue trial activities in Japan.

Consulting Services Agreement:

On November 20, 2014, the Company entered into a ten-year consulting services agreement with Dr. Joshua Hare, its Chief Science Officer (CSO), under which the Company has agreed to pay the CSO $265,000 annually for his part-time services. The initial term of the agreement ended on November 22, 2024; however, with regard to the annual compensation paid to Dr. Hare, the Company continues at present to operate under the same terms on a month-to-month basis.

In addition, the Company entered into a deferred compensation agreement with the CSO to defer payment of the consulting fees earned for services rendered during 2024, which fees will be paid in a lump sum distribution in February 2027. A similar arrangement was also entered into for 2025. On March 4, 2025 and April 11, 2025, the Company entered into stock option agreements with the CSO as part of a Cash-for-Equity Program. These agreements represent settlement of (i) approximately $45,000 in previously accrued consulting fees, and (ii) the CSO's 2024 performance bonus of approximately $131,000, respectively. Pursuant to the Company's Cash-for-Equity Program, the CSO elected to receive this amount in the form of options to purchase 71,254 and 184,878 shares of the Company's Class A Common Stock, respectively. Each award fully vested on July 1, 2025, following stockholder approval at the Company's 2025 annual meeting of stockholders on June 13, 2025, increasing the pool of the shares available for awards under the 2021 Incentive Plan. On July 1, 2025, the Company entered into an additional stock option agreement with the CSO as part of the Cash-for-Equity Program, with such agreement representing settlement of $30,000 in consulting fees earned for services rendered during the three months ended June 30, 2025. Pursuant to the Cash-for-Equity Program, the CSO elected to receive this amount in the form of fully

9. Commitments and Contingencies (cont.)

vested options to purchase 49,219 shares of the Company's Class A Common Stock. On July 15, 2025, the Company granted the CSO options to purchase 109,000 shares of the Company's Class A Common Stock at an exercise price of $1.47 per share, as part of his annual compensation package, with the options vesting quarterly over three years.

As of December 31, 2025 and 2024, the Company had accrued balances due to the CSO of approximately $0.3 million, included in other long-term liabilities.

Manufacturing Services Agreement:

On February 21, 2024, the Company entered into a five-year Supply Agreement with a third-party biotechnology company developing multiple, novel secretomes ("Secretome"), to address a spectrum of diseases driven by pathological processes, to manufacture, test, release, and supply Secretome with cardiac stem cells (the "Product") to be used in Phase 1 and Phase 2 clinical trials (the "Secretome Agreement"). The Company bills Secretome on a variable fee basis for quality control, in process, release, and stability testing service items. Secretome also pays a monthly manufacturing suite reservation fee and hourly fee for project management services.

Following the initial five-year term, the Secretome Agreement may be renewed for additional successive two-year terms upon the mutual written agreement of the parties. Either party may terminate the agreement for cause and upon notice in the event of a material breach, within (i) 30 days of an uncured material breach that is not a payment default or (ii) 10 days for an uncured payment default. The Secretome Agreement further provides that either party may terminate the agreement at any time upon 90 days' notice to the other party.

During 2025, activities under the Secretome Agreement have substantially decreased. No additional manufacturing or development activities are planned, and the Company does not anticipate significant future revenue under this arrangement.

For the year ended December 31, 2025, the Company has earned revenues of $0.2 million under the Secretome Agreement.

Exclusive Licensing Agreements:

UM Agreements

On November 20, 2014, the Company entered into an Exclusive License Agreement with UM (the "UM License") for the use of certain Aging-related Frailty Mesenchymal Stem Cell ("MSC") technology rights developed by our CSO at UM. The UM License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how specifically related to the development of the culture-expanded MSCs for Aging-related Frailty used at the Human-induced pluripotent stem cell-derived mesenchymal stem cells ("IMSCs"), all standard operating procedures used to create the IMSCs, and all data supporting isolation, culture, expansion, processing, cryopreservation and management of the IMSCs.

The Company is required to pay UM (i) a license issue fee of $5,000, (ii) a running royalty in an amount equal to three percent of annual net sales on products or services developed from the technology, payable on a country-by-country basis beginning on the date of first commercial sale through termination of the UM License Agreement, and which may be reduced to the extent we are required to pay royalties to a third party for the same product or process, (iii) escalating annual cash payments of up to $50,000, subject to offset. The agreement extends for up to 20 years from the last date a product or process is commercialized from the technology and was amended in 2017 to modify certain milestone completion dates as detailed below. In 2021 the license fee was increased by an additional $100,000, to defray patent costs. In addition, the Company issued 11,039 unregistered shares of Class A common stock to UM.

9. Commitments and Contingencies (cont.)

The milestone payment amendments shifted the triggering payments to three payments of $500,000, to be paid within six months of: (a) the completion of the first Phase 3 clinical trial of the products (based upon the final data unblinding); (b) the receipt by the Company of approval for the first new drug application ("NDA"), BLA, or other marketing or licensing application for the product; and (c) the first sale following product approval.

The Company has the right to terminate the UM License upon 60 days' prior written notice, and either party has the right to terminate upon a breach of the UM License. To date, the Company has made payments totaling $0.5 million to UM, and as of December 31, 2025 and 2024, in the accompanying balance sheets, the Company had accrued $7,500 and $50,000 in milestone fees payable to UM, respectively.

The Company also entered into an additional Exclusive License Agreement with UM, signed and effective as of July 18, 2024, for technology rights developed by our CSO at UM. This License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how, SOPs, data and other all other rights related to UMP-144, entitled "A method to derive GHRHR+ cardiomyogenic cells from pluripotent stem cells (PSCs) for therapeutic and pharmacologic applications". UM retained a non-exclusive, royalty-free, perpetual, irrevocable, worldwide right to practice, make, and use the Patent Rights or Technology for any non-profit purposes, including educational, and research purposes. In addition to those certain other royalty payments that would be due should the Company's sublicense of the technology result in revenue, the Company also agreed to the following additional milestones and payments: $150,000 upon completion of the first Phase 3 Clinical Trial; and $250,000 upon issuance of a biologics license application or new drug application based on the licensed technology. The Company has the right to terminate the new UM License for convenience upon 90 days' prior written notice, and both parties have additional termination rights for material breach of the agreement.

To date, the Company has made payments totaling $5,000 to UM, and as of December 31, 2025, the Company had not yet accrued any milestone fees payable to UM.

CD271

On December 22, 2016, the Company entered into an exclusive license agreement with an affiliated entity of Dr. Joshua Hare, JMH MD Holdings, LLC ("JMHMD"), for the use of CD271 cellular therapy technology, pursuant to which the Company is required to pay JMHMD a running royalty in an amount equal to one percent of the annual net sales of the licensed product(s) used, leased, or sold by or for the Company by any sub-licensees, payable on a country-by-country basis beginning on the date of first commercial sale and ending on the latter of expiration of the last to expire patent rights in such country or ten years from the first commercial sale in such country (provided that if all claims within the patent rights have expired or been finally deemed invalid then the royalty will be reduced by 50%), and which may also be reduced to the extent the Company is required to pay royalties to a third party for the same product or process.

Under the agreement, the Company is required to use commercially reasonable efforts to achieve the following milestones: (i) submit an investigational new drug application to FDA (or international equivalent) within one year of the effective date of agreement, (ii) initiate a clinical trial utilizing bone marrow derived CD271+ Precursor Cells within three years of the effective date; provided, that any of the milestones may be extended for up to six months for a total of three times by notice and payment of a five thousand dollar extension fee. The agreement is to remain in effect until either the date all issued patents and filed patent applications have expired or been abandoned, or 20 years after the date of FDA approval of the last commercialized product or process arising from the patent rights whichever comes later. If the Company sublicenses the technology, it is also required to pay an amount equal to 10% of the net sales of the sub-licensees.

There were no license fees due for the years ended December 31, 2025 and 2024 pertaining to this agreement.

9. Commitments and Contingencies (cont.)

Other Royalty

Under the grant award agreement with the Alzheimer's Association, the Company may be required to make revenue sharing or distribution of revenue payments for products or inventions generated or resulting from this clinical trial program. The potential payments, although not currently defined, could result in a maximum payment of five times (5x) the award amount of $3.0 million.

Contingencies — Legal

From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. For the year ended December 31, 2025, the Company is not aware of any legal proceedings or material developments requiring disclosure.

10. Employee Benefits Plan

The Company sponsors a defined contribution employee benefit plan (the "Plan") under the provisions of Section 401(k) of the Internal Revenue Code. The Plan covers substantially all full-time employees of the Company who are eligible upon date of hire. Contributions to the Plan by the Company are at the discretion of the Board of Directors.

The Company contributed approximately $0.3 million and $0.2 million to the Plan during the years ended December 31, 2025 and 2024, respectively.

11. Income Taxes

The tax effects of temporary differences and net operating loss ("NOL") carryforwards that gave rise to significant portions of the deferred tax assets and deferred tax liabilities were approximately as follows at December 31, 2025 and December 31, 2024 (in thousands):

	2025	2024
Deferred tax assets:		
Net operating loss carry forwards	$ 15,299	$ 10,870
ASC 842 Lease liability	204	361
Equity based compensation	283	244
Fixed Assets	—	—
Intangible assets	183	158
Capitalized research & development expenses	4,840	4,283
Tax credits	1,986	1,866
Accrual to cash adjustment	—	—
Other	606	466
Total deferred tax assets	23,401	18,248
Valuation allowance	(23,354)	(18,014)
Deferred tax assets, net of valuation allowance	47	234
Deferred tax liabilities:		
ASC 842 Right-of-use asset	(127)	(220)
Depreciation and amortization	80	(14)
Total deferred tax liabilities	(47)	(234)
Deferred tax assets and liabilities, net of valuation allowance	$ —	$ —

11. Income Taxes (cont.)

As of December 31, 2025, the Company had NOL carryforwards for federal purposes of approximately $61.4 million, all of which have no expiration. The Company also had state NOL carryforwards of approximately $55.4 million, all of which have no expiration. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points in shares owned by any 5% owner. In addition, the NOL carry forwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company recorded a valuation allowance of $23.4 million and $18.0 million as of December 31, 2025 and December 31, 2024, respectively. The increase of $5.4 million is related to primarily to additional NOL carryforwards that are not more likely than not to be utilized.

There are no unrecognized deferred tax liabilities for temporary differences related to investments in foreign subsidiaries or foreign corporate joint ventures as of December 31, 2025.

For the year ended December 31, 2025, the Company adopted ASU 2023-09 on a retrospective basis. The following table is a reconciliation of the U.S. federal statutory rate of 21.0% to our effective tax rate for the years ended December 31, 2025 and 2024, in accordance with the guidance in ASU 2023-09.

	2025		2024	
	Amount	Rate	Amount	Rate
Federal statutory tax rate	$ (4,767)	21.0%	$ (3,353)	21.0%
State and local income taxes, net of federal income tax effect[1]				
State and local income taxes	(851)	3.8	(625)	3.9
Changes in valuation allowances	851	(3.8)	625	(3.9)
Effects of changes in tax laws or rates enacted in the current period	—	—	—	—
Foreign tax effects	—	—	—	—
Effects of cross-border tax laws	—	—	—	—
Tax Credits				
Research and development tax credits	(346)	1.5	(573)	3.6
Changes in valuation allowances	346	(1.5)	573	(3.6)
Changes in valuation allowances	4,142	(18.2)	3,040	(19.0)
Nontaxable or nondeductible items	222	(1.0)	253	(1.6)
Changes in unrecognized tax benefits	—	—	—	—
Other adjustments	403	(1.8)	60	(0.4)
Income tax expense and effective tax rate	$ —	—%	$ —	—%

(1) State taxes in Florida make up the majority (greater than 50 percent) of the tax effect in this category

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2025, there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception and as such, tax years subject to potential tax examination could apply from 2021, the earliest year with a net operating loss carryover, because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the years ended December 31, 2025 and 2024.

The Company has not made material income tax payments to any jurisdictions for the year ending December 31, 2025.

12. Loss Per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. We have outstanding equity-based awards that are not used in the calculation of diluted net loss per share because to do so would be anti-dilutive.

The following instruments (in thousands) were excluded from the calculation of diluted net loss per share because their effects would be antidilutive:

	December 31,	
	2025	2024
RSUs	1,209	806
Stock options	658	121
Warrants	21,920	6,803
Total	23,787	7,730

13. Segment Information

Operating segments are defined as components of an entity for which discrete financial information is available and regularly reviewed by the Chief Operating Decision Maker ("CODM") to allocate resources and assess performance. The Company's CODM is its Chief Executive Officer ("CEO"), and the Company manages its operations as a single operating segment focused on developing regenerative medicines to address unmet medical needs. The Company's measure of segment profit or loss is net loss. The CODM manages and allocates resources to the operations of the Company on a total company basis. Managing and allocating resources on a consolidated basis enables the CEO to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects that are in line with the Company's long-term company-wide strategic goals. Consistent with this decision-making process, the CEO uses consolidated financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources, and setting incentive targets. Operating expenses are used to monitor budget versus actual results. All material long-lived assets of the Company are located in the United States and Company's revenues are derived from the United States, The Bahamas and Israel. The total assets of the one reporting segment are disclosed on the balance sheets as of December 31, 2025 and 2024.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reportable segment:

	Year Ended December 31,	
	2025	2024
Revenues[1]	$ 1,199	$ 2,392
Less:		
Cost of revenues	396	508
R&D costs[2]	4,235	2,799
G&A costs[3]	6,184	5,646
Personnel costs[4]	12,444	9,002
Other segment items[5]	644	410
Net loss	$ (22,704)	$ (15,973)

(1) Includes Contract Manufacturing and Clinical Trial revenue
(2) Includes Clinical Development, Research & Discovery, CMC
(3) Includes Executive, Finance, Legal, Business Operations
(4) Includes compensation, benefits and equity-based compensation
(5) Includes depreciation and amortization, (interest income) and other specific charges

14. Subsequent Events

PIPE Financing

On March 11, 2026, the Company completed an initial closing of a private placement transaction with certain institutional and accredited investors, pursuant to which an aggregate of 6,013,384 shares of common stock were sold at a purchase price of $0.52 per share and 11,873.04 shares of Series A Preferred Stock convertible into an aggregate of 22,832,770 shares of common stock were sold at a purchase price of $1,000.00 per preferred share.

Additionally, the Company agreed to sell to the investors an interest in 50% of proceeds received (after deducting necessary, documented third-party fees or charges) from the potential future sale of a Rare Pediatric Disease Priority Review Voucher to the extent received from the U.S. FDA in connection with the Company's laromestrocel program for Hypoplastic Left Heart Syndrome (HLHS). The aggregate gross proceeds from the initial closing were approximately $15.9 million, before deducting placement agent fees and other private placement expenses. H.C. Wainwright, who acted as the exclusive placement agent for the private placement, received a cash fee equal to 7.0% and a management fee equal to 1.0%, of the aggregate gross proceeds raised.

The Company also issued to designees of the Placement Agent (or their assignees) unregistered warrants to purchase up to 2,019,231 shares of Common Stock (the "Placement Agent Warrants"). The Placement Agent Warrants will have an exercise price of $0.65 per share which represents 125% of the Share Price), are exercisable immediately upon issuance and have a term of five years from the date of issuance. Each Placement Agent Warrant is exercisable for one share of Common Stock. Neither the Placement Agent Warrants nor the shares of Common Stock issuable upon exercise thereof have been registered under the Securities Act.

Subject to satisfaction or waiver of certain conditions discussed below, the Company also agreed to issue and sell to the investors additional shares of common stock and Series A Preferred Stock, respectively, in a second closing, for additional gross proceeds of approximately $15.0 million, before deducting placement agent fees and other private placement expenses. The second closing would occur upon satisfaction or waiver (by Investors holding at least a majority in interest of the Securities then held by the Investors, on an as-converted basis) of the closing conditions set forth under the Purchase Agreement, including (i) the Company's achievement of Phase 2b study results for HLHS demonstrating statistical significance of the primary endpoint(s) as agreed between the Company and the U.S. FDA (the "Milestone") and (ii) achievement of a volume weighted average price per share of common stock equal to or greater than $1.85 with aggregate trading volume of at least 25,000,000 shares (in each case, subject to appropriate, proportional adjustment for any stock splits or combinations of the common stock occurring after the date of the Purchase Agreement) during any ten consecutive trading days prior to expiration of the 30 trading days following the date of the Company's first announcement via press release or a Current Report on Form 8-K of the occurrence of the Milestone.

Corporate Information

EXECUTIVE MANAGEMENT TEAM

STEPHEN H. WILLARD
Chief Executive Officer

JOSHUA M. HARE, MD, FACC, FAHA
Chief Science Officer and Executive Chairman

LISA LOCKLEAR
Chief Financial Officer, Executive Vice President and Treasurer

NATALIYA AGAFONOVA, MD
Chief Medical Officer

PAUL LEHR, JD
General Counsel and Secretary

DEVIN BLASS
Chief Technology Officer and Senior Vice President of Chemistry, Manufacturing and Controls

BOARD OF DIRECTORS

JOSHUA M. HARE, MD, FACC, FAHA – Executive Chairman

ROGER HAJJAR, MD

GEORGE PALETTA, JR., MD

ROCK SOFFER

URSULA UNGARO, JD

INVESTOR RELATIONS

Inquiries and requests for information, including copies of Longeveron's Annual Report on Form 10-K, may be obtained without charge by contacting Longeveron at info@longeveron.com or visiting our website at www.longeveron.com.

ANNUAL MEETING - VIRTUAL

July 1, 2026, at 11:00 a.m. Eastern Time.
Accessed through a live webcast at
https://vote.colonialstock.com/LGVN2026

TRANSFER AGENT

Colonial Stock Transfer
7840 S. 700 E.
Sandy, UT 84070

INDEPENDENT AUDITORS

CBIZ CPAs P.C.
185 Asylum Street, 25th Floor
Hartford, CT 06103

This annual stockholder report contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that reflect our current expectations about our future results, performance, prospects and opportunities. Such forward-looking statements can involve substantial risks and uncertainties. All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Factors that could cause actual results to differ materially from those expressed or implied in any forward-looking statements contained in this report include, but are not limited to, statements about our cash position and need to raise additional capital, the difficulties we may face in obtaining access to capital, and the dilutive impact it may have on our investors; our financial performance, and ability to continue as a going concern; the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements; the ability of our clinical trials to demonstrate safety and efficacy of our investigational product candidates, and other positive results; the timing and focus of our ongoing and future preclinical studies and clinical trials, and the reporting of data from those studies and trials; the size of the market opportunity for certain of our investigational product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting; our ability to scale production and commercialize the investigational product candidate for certain indications; the success of competing therapies that are or may become available; the beneficial characteristics, safety, efficacy and therapeutic effects of our investigational product candidates; our ability to obtain and maintain regulatory approval of our investigational product candidates in the U.S. and other jurisdictions; our plans relating to the further development of our investigational product candidates, including additional disease states or indications we may pursue; our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available and our ability to avoid infringing the intellectual property rights of others; the need to hire additional personnel and our ability to attract and retain such personnel; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events.