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, 2024

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	**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 $12,438,864 as of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter).

As of February 17, 2025, the registrant had 13,473,898 shares of Class A common stock, $0.001 par value per share, and 1,454,005 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. This 10-K contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this 10-K, 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 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 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 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 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 product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates in the U.S. and other jurisdictions;
- our plans relating to the further development of our 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. 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. We operate in a highly competitive and rapidly changing environment; therefore, new risk factors can arise, and it is not possible for management to predict all such risk factors, nor to assess the impact of all such risk factors on our business or the extent to which any individual risk factor, or combination of risk factors, may cause results to differ materially from those contained in any forward-looking statement.

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. We do not undertake any obligation to update these statements to reflect events or circumstances occurring after the date this 10-K is filed.

PART I

Item 1. Business

Overview

We are a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. The Company's lead investigational product is Lomecel-B™, an allogeneic Mesenchymal Stem Cell ("MSC") formulation sourced from the bone marrow of young, healthy adult donors. Lomecel-B™ has multiple potential mechanisms of action that promote tissue repair and healing with broad potential applications across a spectrum of disease areas. The underlying mechanism(s) of action that may lead to tissue repair programs include the stimulation of new blood vessel formation, modulation of the immune system, anti-inflammatory properties, reduction in tissue fibrosis, and the stimulation of endogenous cells to divide and increase the numbers of certain specialized cells in the body.

We are currently pursuing three pipeline indications: Hypoplastic Left Heart Syndrome ("HLHS"), Alzheimer's disease ("AD") and Aging-related Frailty. Our mission is to advance Lomecel-B™ and other cell-based product candidates into pivotal or Phase 3 trials, with the goal of achieving regulatory approvals, subsequent commercialization, and broad use by the healthcare community.

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.

HLHS

Our HLHS program is focused on the potential clinical benefits of Lomecel-B™ as an adjunct therapeutic to standard-of-care HLHS surgery. HLHS is a rare and devastating congenital heart defect in which the left ventricle is severely underdeveloped. As such, babies born with this condition die shortly after birth without undergoing a complex series of reconstructive heart surgeries. Despite the availability of life-saving surgical interventions, clinical studies show that only 50 to 60 percent of affected individuals survive to adolescence. Early clinical study data shows the potential survival benefit of Lomecel-B™ for HLHS patients and supports Longeveron's belief that these data show the potential to alter the treatment landscape for patients with HLHS. We have completed a Phase 1 open-label study ("ELPIS I")[1] that supported the safety and tolerability of Lomecel-B™ for HLHS, when directly injected into the functional right ventricle ("RV") during the second-stage standard-of-care surgery (adding minimal additional time to the surgical procedure). Preliminary data revealed that several indices of right ventricular function show suggestions of either improvement or prevention of deterioration over one year following surgery. Heart transplant-free survival for patients who received Lomecel-B™ intracardiac injection is favorable as compared to historical controls for survival. The ELPIS I trial showed 100 percent transplant-free survival in children up to 5 years after receiving Lomecel-B™, compared to a 20 percent mortality rate observed from historical control data. The improvement in HLHS survival following the Phase 1 ELPIS I clinical trial resulted in scientific presentations at American Heart Association ("AHA") in November 2023 and Congenital Heart Surgeons' Society's 51st Annual Meeting in October 2024.

Based on these findings, the U.S. Food and Drug Administration (the "FDA") granted Lomecel-B™ Rare Pediatric Disease ("RPD") Designation, Orphan Drug Designation ("ODD"), and Fast Track Designation for treatment of infants with HLHS. On September 3, 2024 Longeveron announced a positive Type C meeting with the FDA supporting the advancement of Lomecel-B™. Longeveron is currently conducting a controlled Phase 2b trial ("ELPIS II") to compare the effects of Lomecel-B™ as an adjunct therapeutic versus standard-of-care (HLHS surgery alone). We hope that a positive outcome could add to the clinical data suggesting the clinical benefit of Lomecel-B™ as part of standard-of-care treatment in HLHS patients.

As a result of the Type C meeting, we reached foundational alignment with the FDA on the registrational path to pursue traditional approval for Lomecel-B™ for treatment of HLHS, based on the proposed clinical development program, which includes the ongoing Phase 2b ELIPIS II study as the pivotal study to provide primary evidence of effectiveness.

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[1] Sunjay Kaushal, M.D., Ph.D, Joshua M Hare, M.D., Jessica R Hoffman, Ph.D, Riley M Boyd, BA, Kevin N Ramdas, M.D., MPH, Nicholas Pietris, M.D., Shelby Kutty, M.D., Ph.D, MS, James S Tweddell, M.D., S Adil Husain, M.D., Shaji C Menon, MBBS, M.D., MS, Linda M Lambert, MSN-cFNP, David A Danford, M.D., Seth J Kligerman, M.D., Narutoshi Hibino, M.D., Ph.D, Laxminarayana Korutla, Ph.D, Prashanth Vallabhajosyula, M.D., MS, Michael J Campbell, M.D., Aisha Khan, Ph.D, Eric Naioti, MSPH, Keyvan Yousefi, PharmD, Ph.D, Danial Mehranfard, PharmD, MBA, Lisa McClain-Moss, Anthony A Oliva,

Ph.D, Michael E Davis, Ph.D, Intramyocardial cell-based therapy with Lomecel-B™ during bidirectional cavopulmonary anastomosis for hypoplastic left heart syndrome: The ELPIS phase I trial, *European Heart Journal Open*, 2023.

Alzheimer's Disease

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 we tested three distinct Lomecel-B™ dosing regimens against placebo.

The study demonstrated positive results. The established safety profile of Lomecel-B™ for single and multiple dosing regimens was demonstrated in study data that showed no incidence of hypersensitivity or infusion-related reactions, there were no cases of amyloid-related imaging abnormalities (ARIA), and all Lomecel-B™ treatment groups met the safety primary endpoint and showed slowing/prevention of disease worsening relative to placebo. There were statistically significant improvements in the secondary efficacy endpoint, composite AD score ("CADS") for both the low-dose Lomecel-B™ group and the pooled treatment groups compared to placebo. Other doses also indicated promising results in slowing/prevention of disease worsening. Additionally, a statistically significant 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"). The study indicated potential preservation of brain volumes in some but not all AD related areas of 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).

The results of the CLEAR MIND trial were presented in the Featured Research Session at the 2024 Alzheimer's Association International Conference ("AAIC") in July 2024. The brain volume results measured by MRI results from this trial also were presented at the poster presentation at AAIC. These findings support both the safety and potential therapeutic benefit of Lomecel-B™ in managing mild AD, and we believe lays the groundwork for subsequent trials in this indication. Based on these results, the FDA granted Regenerative Medicine Advanced Therapeutics (RMAT) Designation on July 9, 2024, and Fast Track designation on July 17, 2024, to Lomecel-B™ for the treatment of mild AD.

Additional data from the CLEAR MIND trial was presented as a late breaking poster presentation at the Clinical Trials on Alzheimer's Disease Conference ("CTAD24") in October 2024 in Madrid, Spain.

Based on the totality of the evidence, the FDA granted our request for a Type B meeting and we anticipate meeting with them in late Q1 2025, during which we intend to discuss possible development paths for Lomecel-B™ in mild AD.

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 health span – 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.

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 focus on HLHS. Key elements of our current business strategy are as follows.

- Execution of ELPIS II, a Phase 2b randomized controlled trial set forth in greater detail below, to measure the efficacy of Lomecel-B™ 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.

- Continue to pursue the therapeutic potential of Lomecel-B™ in mild AD. We completed a Phase 2a trial, the ("CLEAR MIND Trial"), which demonstrated the potential benefits of Lomecel-B™ over placebo to maintain cognitive function and slow deterioration of brain structure atrophy, with no safety issues observed. Specifically, the safety primary endpoint was met across all study groups and the trial demonstrated a statistical significance in the second CADS endpoint. Overall, in Lomecel-B™ groups, brain MRI demonstrated that whole brain volume loss was slowed, accompanied by significant preservation of multiple brain regions, including left hippocampus relative to placebo. We plan to continue to analyze the data in order to further develop our clinical development strategy. Our objective is to forge strategic collaborations for the advancement of Lomecel-B™ in addressing AD.
- Limited focus on our international program. In line with the Company's strategic direction for 2025 and moving forward to focus on HLHS and AD as set forth previously, in April 2024, the Company discontinued its clinical trial in Japan to evaluate Lomecel-B™ for Aging-related Frailty. The Company will continue to enroll patients on the Frailty and Cognitive Impairment registry trials in The Bahamas and plans to also launch an Osteoarthritis registry trial.
- Expand our manufacturing capabilities to commercial-scale production. We operate a current good manufacturing practice ("cGMP")-compliant manufacturing facility and produce our own product candidates for testing. We continue to improve and expand our capabilities with the goal of achieving cost-effective manufacturing that may potentially satisfy future commercial demand for potential Lomecel-B™ commercialization.
- 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 Lomecel-B™ and other products domestically and internationally if appropriate approvals are obtained.
- 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.

Clinical Development Pipeline in 2025

We are currently in clinical development of a single product, Lomecel-B™ for three potential indications:

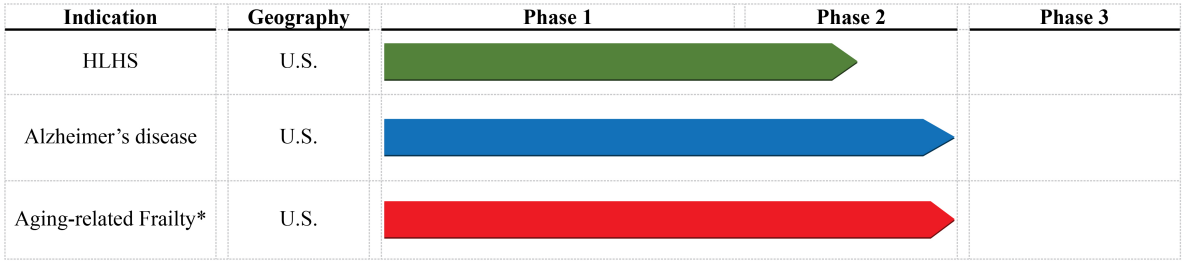

Figure 1: Lomecel-B™ clinical development pipeline

* Not currently active for 2025

Hypoplastic Left Heart Syndrome (HLHS). The FDA granted Lomecel-B™ for the treatment of HLHS a Rare Pediatric Disease ("RPD") Designation (on November 8, 2021), Orphan Drug Designation ("ODD") (on December 2, 2021), and Fast Track Designation (on August 24, 2022). HLHS is a rare congenital heart condition affecting approximately 1,000 newborns in the US 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 currently conducting an ongoing Phase 2b clinical trial (ELPIS II) under FDA IND 017677. ELPIS II is a multi-center, randomized, double-blind, controlled clinical trial designed to evaluate Lomecel-B™ 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 Lomecel-B™ treatment versus standard-of-care surgery alone (38 subjects total: 19 per arm). This trial is presently over 90% enrolled and is funded in part by the NHLBI/NIH. While enrollment completion was initially targeted for the end of 2024, given the relatively small patient population, clinical trial enrollment timing for rare diseases like HLHS is difficult to predict and we anticipate full enrollment will be completed prior to the end of the second quarter of 2025.

ELPIS II is a next-step trial to our completed 10-patient open-label Phase 1 trial (ELPIS I) under the same IND. This Phase 1 trial was designed to evaluate the safety and tolerability of Lomecel-B™ as an adjunct to the second-stage HLHS surgery, and to obtain preliminary evidence of Lomecel-B™ 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 Lomecel-B™, and the potential to improve post-surgical heart function.

All ELPIS I patients had completed long-term follow-up, and 100% 5-years post-Glenn survival data were presented by Principal Investigator Dr. Sunjay Kaushal, Cardiovascular and Thoracic Surgery, University of Nevada, Las Vegas at American Heart Association ("AHA") in November 2023 and Congenital Heart Surgeons' Society's 51st Annual Meeting in October 2024.

We have filed patent applications relating to the administration of Lomecel-B™ 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, 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. Lomecel-B™ treated patients showed an overall slowing/prevention of disease worsening compared to placebo in the completed Phase 2a study (CLEAR MIND) as previously detailed in this report, and met its primary endpoint of safety. These results are consistent with those of our earlier Phase I study[2]. Based on these results, in July 2024, the FDA granted RMAT designation and Fast Track designation to Lomecel-B™ for the treatment of mild AD. We believe Lomecel-B™ is the only product candidate to be granted RMAT designation for mild AD to date.We intend to forge strategic collaborations, consider potential partnerships, or pursue other available pathways or opportunities for the advancement of Lomecel-B™ in addressing AD.

We have filed patent applications relating to the treatment of AD using Lomecel-B™ 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 Lomecel-B™ in the Bahamas, Taiwan, in addition to a PCT application.

Aging-related Frailty. Aging-related Frailty is a life-threatening geriatric condition that disproportionately increases risks for poor clinical outcomes from disease and injury. While the definition of Aging-related Frailty lacks consensus, would be a new indication from a regulatory standpoint, and has no approved pharmaceutical or biologic treatments, there are a number of companies now working to develop potential therapeutics for this unmet medical need.

We have previously completed two U.S. clinical trials under FDA IND 016644. One is a multi-center, randomized, placebo-controlled Phase 2b trial which showed that a single infusion of Lomecel-B™ significantly improved 6-Minute Walk Test ("6MWT") distance 9 months after infusion (although results were inconclusive at six months after infusion), and also showed a dose-dependent increase in 6MWT distance 6 months after infusion. The second is a multi-center, randomized, placebo-controlled Phase 1/2 trial ("HERA Trial") intended primarily to evaluate safety, and explore the effect Lomecel-B™ may have on specific biomarkers of immune system function in older, frail individuals receiving the high dose influenza vaccine, as well as to evaluate the potential effects of Lomecel-B™ on signs and symptoms of Aging Frailty. Results from this study showed that Lomecel-B™ was generally safe and well tolerated in patients with Aging-related Frailty. Additionally, hemagglutinin inhibition ("HAI") assay results in the Lomecel-B™ and placebo groups to influenza were not statistically different, indicating Lomecel-B™ does not suppress the immune system.

We have filed patent applications relating to the administration of Lomecel-B™ for Aging-related Frailty in Australia, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, Singapore, South Korea, New Zealand, South Africa, Taiwan, the Bahamas and the United States.

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 Lomecel-B™ for our 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 enable quick scale-up of production upon approval of any of our candidates in a particular country.

Our current good manufacturing process ("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 products for use in clinical trials. The facility is in compliance with FDA regulations in the Code of Federal Regulations 21, Parts 210 and 211.

Lomecel-B™, consists of human allogeneic bone-marrow derived mesenchymal stem cells 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. Lomecel-B™ 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 Lomecel-B™ 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 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 product candidates is a competitive advantage. Over time, as needed and appropriate, we expect to expand regional manufacturing capacity and potentially add external supply nodes to meet projected product requirements for commercialization. We believe that anticipated future clinical and commercial demand for Lomecel-B™ 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 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 to address a spectrum of diseases driven by pathological processes, to manufacture, test, release, and supply the third-party with cardiac stem cells (the "Product") to be used in Phase 1 and Phase 2 clinical trials. The Company received an initial start-up payment upon signing and will thereafter bill on a variable fee basis for quality control, in process, release, and stability testing service items. The Company will receive a fee for product management and manufacturing services.

[2] Mark Brody, Marc Agronin, Brad J. Herskowitz, Susan Y. Bookheimer, Gary W. Small, Benjamin Hitchinson, Kevin Ramdas, Tyler Wishard, Katalina Fernández McInerney, Bruno Vellas, Felipe Sierra, Zhijie Jiang, Lisa McClain-Moss, Carmen Perez, Ana Fuquay, Savannah Rodriguez, Joshua M. Hare, Anthony A. Oliva Jr., Bernard Baumel. "Results and insights from a phase I clinical trial of Lomecel-B™ for Alzheimer's disease" (2023) Alzheimer's & Dementia: The Journal of the *Alzheimer's Association 19:261-273.*

Commercialization

We currently have no established sales, marketing or product distribution infrastructure. In order to commercialize any of our 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 product candidates through development toward regulatory approval, we plan to evaluate several options for each 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 Lomecel-B™), 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 over 2,936 worldwide as of December 2024.

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 mesenchymal stem cells 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; 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**
Athersys	USA	Ischemic Stroke, Trauma, Acute Respiratory Distress Syndrome
BioCardia	USA	Ischemic heart failure; Chronic Myocardial Ischemia
BlueRock Therapeutics	USA	Parkinson's disease
BrainStorm Cell Therapeutics	Israel	Alzheimer's disease; Multiple Sclerosis; Lateral Scelerosis; 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; Acute Respiratory Distress Syndrome
Healios KK	Japan	Ischemic Stroke; Acute Respiratory Distress Syndrome
Kadimastem	Israel	Alzheimer's disease; Multiple Sclerosis; Diabetes
Medipost	South Korea	Osteoarthritis; Bronchopulmonary Dysplasia
Mesoblast	Australia	Heart failure; HLHS; GvHD; ARDS; Crohn's Disease
ReNeuron	UK	Ischemic stroke
SanBio Co Ltd	USA	Ischemic stroke; Brain Injury
Stemedica Cell Technologies	USA	Ischemic Stroke; Alzheimer's disease; Heart failure; AMI

Hypoplastic Left Heart Syndrome Competitive Intelligence Research

Per ClinicalTrials.gov, as of February 6, 2025, there were 39 interventional clinical trials and 25 observational studies listed studying HLHS in a pediatric patient population across all stages of development. Among those there were 2 surgical intervention trials which are actively enrolling patients and no medical intervention studies. There were 22 clinical studies which were completed in HLHS patient populations and all of them were conducted as an investigator-sponsored trial.

Alzheimer's Disease Competitive Intelligence Research

There are also many pharmaceutical and biotechnology companies that are conducting clinical trials of various therapeutics for the treatment of AD. Per ClinicalTrials.gov, as of February 6, 2025, there were 3,608 studies listed on the site studying Alzheimer's disease, including all stages (ongoing, completed, terminated, withdrawn) and all interventions. Five of them were listed as active clinical studies with cell therapies (4 interventional and 1 observational).

Mesoblast

On December 18, 2024, the FDA approved Ryoncil (remestemcel-L-rknd), an allogeneic (donor) bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft-versus-host disease (SR-aGVHD) in pediatric patients 2 months of age and older. Ryoncil is the first FDA-approved MSC therapy. It contains mesenchymal stem cells, which are a type of cell that can have various roles in the body and can differentiate into multiple other types of cells. These mesenchymal stem cells are isolated from the bone marrow of healthy adult human donors.

We believe the recent approval of the Mesoblast product Ryoncil by the FDA represents a positive development for Longeveron, as it belongs to the same class of cell therapy as Lomecel-B™.

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 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. This portfolio includes patent applications directed to use of allogeneic mesenchymal stem cells to treat sexual dysfunction. We also have in-licensed a patent family directed to methods of use of CD271+ MSC precursor cells. Our patent applications contain claims that, if allowed, specifically protect the use of our product in individuals with Aging-related Frailty, immunosenescence, and other age-related diseases. 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 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 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™ mesenchymal stem cells 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 products or products that are similar to our products 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 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 date of filing 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 products 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 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.

We 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 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 agreements 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 clinical candidates.

Company-Owned Intellectual Property

Mesenchymal Stem Cells as Vaccine Adjuvants and Methods for Using the Same. The claims within this patent application 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 mesenchymal stem cells in a subject that exhibits "inflammaging." In this family we have one issued patent in Australia and one issued patent in the United States. We have two 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 Mesenchymal Stem Cells 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. It is believed that raising or lowering specific biomarkers after therapeutic intervention by a minimum amount may provide broad protection from an intellectual property standpoint and reflects clinical goals of treatment and treatment response.

In this family we own pending applications in the Bahamas, Taiwan, 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 China, Taiwan, 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 applications in The Bahamas and 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, and we own a patent in Japan. 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 mesenchymal stem cells 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 Mesenchymal Stem Cells in Treatment of Juvenile Hypoplastic Left Heart Syndrome. This patent family is directed to treatment of HLHS with allogeneic mesenchymal stem cells. 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 Mesenchymal Stem Cells for Aging-related Frailty. This patent family relates to administration of mesenchymal stem cells for Aging-related Frailty. In this family we own pending applications in Taiwan, the Bahamas, and the PCT. 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. 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 Mesenchymal Stem Cells. This patent family relates to administration of mesenchymal stem cells 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 Mesenchymal Stem Cells. This patent family relates to administration of mesenchymal stem cells 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 a potency assay. The family currently consists of three unpublished United States provisional patent applications. Further applications in this family are anticipated to be filed by the conclusion of the first quarter of 2025.

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 mesenchymal stem cells 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"), biologics application ("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. Food and Drug Administration, 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) UMP-438 titled "Method of Determining Responsiveness to Cell Therapy in Dilated Cardiomyopathy." The additional technology 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 applications pending in Australia, Canada, China, Israel, and Japan.

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 $365,000 to UM, and as of December 31, 2024, we had accrued $50,000 in milestone fees payable to UM and $15,000 for patent related reimbursements based on the estimated progress to date.

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" and having inventors Joshua Hare and Konstantinos Chatzistergos. 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 certain 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: (c) $150,000 upon completion of the first Phase 3 Clinical Trial; and (d) $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, 2024, the Company (i) had accrued but not yet paid $21,307 in reimbursement of previously incurred patent expenses payable to UM and (ii) 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 investigational new drug application 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. The Company to date 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 $19,000 for each of the years ended December 31, 2024 and 2023, 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 Mesenchymal Stem Cell 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).

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.	Allowed	Allowed/Published
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 Lomecel-B™ as a biologic drug (i.e., a biologic) through the biologics license application ("BLA") process under the jurisdiction of the Center for Biologics Evaluation and Research ("CBER"). We intend to work with the FDA to confirm that a BLA is the most appropriate pathway and that CBER will be the FDA center responsible for review and licensure (i.e., approval). However, the FDA may disagree with us, in which case we will follow the FDA's recommendation. For future product candidates we will also confirm the appropriate approval pathway (i.e., BLA or new drug application ("NDA")) and the appropriate FDA center with regulatory oversight (i.e., CBER or the Center for Drug Evaluation and Research ("CDER")).

U.S. Biologic Drug Development Process

In the U.S., biologic drugs—or simply "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 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;
- approval by an independent institutional review board ("IRB") at each clinical site (or by one "commercial IRB") before each trial may be initiated;
- performance of 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 all clinical trials;
- satisfactory outcome of 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; 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 is required for a BLA varies widely depending upon the specific type of 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. 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 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 product candidate and the size of the patient population:

- Phase 1: The 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 products for severe or life-threatening diseases when the product 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 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 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 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 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, a 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. 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 product 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 products on an expedited basis if the products 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 regenerative medicine advanced therapy ("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 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 Lomecel-B™ 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, products 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 product 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 Lomecel-B™ for the treatment of HLHS on August 4, 2022 and for the treatment of mild AD on July 16, 2024.

Priority Review Designation. A product 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 product 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 a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious condition and preliminary clinical evidence indicates that the product 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 a product receives this designation, then the FDA will work to expedite the development and review of that product. 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. A drug product intended to treat a serious condition may be eligible for accelerated approval upon a determination that the product 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 a 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 product candidates 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 Lomecel-B™ 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 Lomecel-B™ (or any other 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 Lomecel-B™ 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 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 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 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 FDA in practice. Although 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 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 products 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 $26,125 per claim submitted and twice 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 $174,172 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 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 $105,563 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 $13,508 to $27,018 for each false claim, 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 FCA established several separate criminal penalties for making false or fraudulent claims to insurance companies and other non-governmental payers of healthcare services. Under the FCA, 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 $10,000 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 the Health Insurance Portability and Accountability Act of 1996 ("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 biological 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 biological 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 from 15.1% to 23.1% of the Average Manufacturer Price ("AMP") or the difference between AMP and "best price," whichever is greater; 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 is focused on increasing competition in several industries, including the pharmaceutical and biotechnology industries. Among other things, the Executive Order directs 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 encourages 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.

It is unclear how the second Trump Administration may approach healthcare reform efforts, nor is it clear whether other legislative changes will be adopted, if any, or how such changes may impact healthcare reform efforts of prior Administrations.

Human Capital Management

As of December 31, 2024, we had 25 full-time employees plus 1 employee on leave of absence, zero part-time employees and zero full-time consultants. Among those employees, 2 had M.D. and 4 had Ph.D. degrees, 2 are Certified Public Accountants, and 1 has a J.D. degree. Of these full-time employees, 18 are engaged in research and development activities. 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 Amendment. 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 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;
- Adverse global conditions, including macroeconomic uncertainty, may negatively impact our financial results;
- We have a history of losses, 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;
- There are no FDA-approved allogeneic, cell-based therapies for Aging-related Frailty, AD, or other aging-related conditions, nor HLHS or other cardiac-related indications. This could complicate and delay FDA approval of our product candidate for these indications, or other indications we study or will study;
- Ethical and other concerns surrounding the use of stem cell therapy or human tissue may negatively affect public perceptions of us or our future products or product candidates, or may negatively affect regulatory approval of our future products or product candidates, thereby reducing demand for our future products,
- The use of our 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; and
- We face risks related to our contract development and manufacturing business.

Risks Related to Intellectual Property

- If our trade secret and patent position does not adequately protect our 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 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;
- Third-party claims of intellectual property infringement may prevent or delay our product development efforts; and
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Risks Related to Regulatory Approval and Other Government Regulations

- If we are not able to successfully develop and commercialize our product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations;
- We cannot market and sell our product candidates in the U.S. or in other countries if we fail to obtain the necessary regulatory approvals;
- Final marketing approval of our product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which could adversely affect our ability to generate operating revenues;
- We may not be able to secure and maintain research institutions to conduct our clinical trials;
- Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations; and
- Even if we receive regulatory approval of Lomecel-B™ or any of our other 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 product candidates.

Risks Related to Our Dependence on Third Parties

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

Risks Related to the Discovery, Development and Commercialization of Our 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

- 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.

- Provisions in our certificate of incorporation, as amended ("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.
- Failure to maintain our share price above the minimum bid price requirement established by Nasdaq could result in the delisting of our Class A common stock on the Nasdaq Capital Market. The loss of our Nasdaq listing would in all likelihood make our Class A common stock significantly less liquid and adversely affect its value.

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

- We have never commercialized a 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; and
- 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.

Item 1A. Risk Factors

In addition to the other information in this 10-K, the following risk factors should be considered carefully in evaluating us. You should carefully consider 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 deciding whether to invest in our Class A common stock or to maintain or change your investment. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, 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 those set forth below. For a summary of these risk factors, please see "Risk Factors Summary" beginning on page 23 of this 10-K.

Risks Related to our Business

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, product candidate development and manufacturing, securing related intellectual property rights and conducting clinical trials of our Lomecel-B™ cellular therapy. 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.

If the potential of our 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 product candidates to treat diseases. We have not yet proven in clinical trials that our product candidates will be a safe and effective treatment for any disease or condition. Our 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 product candidates to treat disease is not realized, the value of our technology and our development programs could be significantly reduced. Because our product candidates are based on mesenchymal stem cells, any negative developments regarding the therapeutic potential or side effects of our mesenchymal stem cells, or regarding scientific and medical knowledge about mesenchymal stem cells 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 product candidates based on new technologies. The novel nature of our product candidates creates significant challenges in regards 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 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 or other cardiac-related indications. This could complicate and delay FDA approval of our 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 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 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 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 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 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 product candidates, the market may not understand or accept them. We are developing 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 products and their perceived advantage over alternative treatment methods;
- our ability to demonstrate that our cell-based products 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 product candidates or candidates of others that are cell based;
- 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
- the cost of our products and the reimbursement policies of government and third-party payors.

If the health care community does not accept our 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 product candidates as needed to complete our clinical trials, and if our trials are successful and our products 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 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 mesenchymal stem cells through our proprietary manufacturing methods utilizes biologic growth media that may be in limited supply. Our 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 product candidates. Moreover, even if our clinical trials are successful and we obtain marketing approval for our 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 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 product candidate or 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 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 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 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 product candidates, or may negatively affect regulatory approval of our future products or product candidates, thereby reducing demand for our future products.

The commercial success of our 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 mesenchymal stem cells 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 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 mesenchymal stem cells 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 product candidates or 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 health care 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 product candidates under development by us now or in the future, or any products manufactured or marketed by us, non-competitive or otherwise obsolete.

Sales of our products may involve a lengthy sales cycle.

Many factors are expected to influence the sales cycle for products once they are approved. These factors include the future state of the market, the perceived value of our 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 approved products.

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, 2024, we had $19.2 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.

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

Global outbreaks of epidemics, pandemics, and other public health risks, such as COVID-19, continue to impact countries, communities, supply chains and markets. For example, the COVID-19 pandemic has impacted our Bahamas Registry Trial business. It is also possible that the COVID-19 pandemic or other 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 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 the virus causing COVID-19 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 the epidemics, pandemics, and other public health risks are generally fluid and continue 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 products, 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, increased 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 Russian invasion of the Ukraine, the Israeli-Palestinian conflict, the withdrawal of the United Kingdom from the European Union, 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 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, 2024 and 2023, had an accumulated deficit of approximately $109.6 million and $85.0 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, 2024, we had cash and cash equivalents of $19.2 million. We currently believe that our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025 based on our current operating budget and cash flow forecast. However, as a result of a successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. Our operating expenses and capital expenditure requirements are expected to accelerate in 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing/capital raises/non-dilutive funding options 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 we will be able to attain future financing at terms favorable to us or at all. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect. We currently have no credit facility or committed sources of capital.

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, 2024, 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, 2024 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 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 78 of this report.

The use of our 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 products, we face an inherent risk of product liability claims. None of our 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 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 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 products or termination of clinical trials;
- FDA withdrawal of marketing approval of products or suspension or revocation of an IND for a 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 provide contract development and manufacturing services to a third-party and may, in the future, provide similar services to a limited number of customers that are developing their own cellular therapy treatments. Losing any customer of our contract

development and manufacturing services could have a significant impact on the income generated from this division of our business. Whether we are developing and manufacturing our product candidates or products or product candidates for our customers, similar regulatory, ethical, supply chain, and demand risks apply. Assisting customers in developing a product or 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. Our success with respect to the contract manufacturing operations of our organization is largely dependent on forces outside of our control as our success in dependent on the success of our customers' products and product candidates. Our customers may have to overcome the same or similar obstacles that we face in bringing their product to market. 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 product candidates could result in recalls, legal liabilities, and impact our relationship with current and future customers. The cell therapy development and manufacturing industry is highly competitive. New companies entering the market could result in pricing pressures, reduced margins, and the loss of market share. Our focus has been and will continue to be on developing our own product candidates, while our competitors may only be focused on manufacturing cell therapies for their customers. Splitting our focus may give other contract manufacturing companies a competitive edge. Furthermore, jurisdictions outside of the United States may have other regulatory requirements that we cannot meet without incurring costs and expenses. Customers looking to obtain regulatory approval in the jurisdictions may engage with competitors that already meet the regulatory requirements of such jurisdictions. Our ability to compete effectively depends on our reputation, quality of service, current technology, regulatory approval, and operational efficiency.

Risks Related to Intellectual Property

If our trade secret and patent position does not adequately protect our 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 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 mesenchymal stem cells. 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 mesenchymal stem cells. 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 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 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 products might not have the robust protection we currently expect to enjoy. The background technologies used in the development of our product candidates are known in the scientific community, and it may be possible to duplicate the methods we use to create our 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 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 product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates, methods of making product candidates, and methods of using 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 Lomecel-B™ mesenchymal stem cells 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 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 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 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 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 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 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 product candidates. They might seek an exclusion order from the International Trade Commission to prevent import of our 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 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 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 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 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 products, be an early entrant to the market and manufacture, market, and sell our 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 product candidates are approved by the FDA, then potential competitors who seek to introduce generic versions of our product candidates may seek to take advantage of the abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with our 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 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 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 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 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 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 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 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 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 product candidates, patents directed to our 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 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 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 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 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 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 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.

Risks Related to Regulatory Approval and Other Government Regulations

If we are not able to successfully develop and commercialize our 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 product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate that our product candidates are safe and effective, and we must obtain required regulatory approvals. Our early-stage product candidates may fail to perform as we expect. Moreover, our product candidates in later stages of development may fail to show the required safety and effectiveness for approval despite having progressed successfully through preclinical or initial clinical testing. We may need to devote significant additional research and development, financial resources, and personnel to develop commercially viable products. If our 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.

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

- regulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other regulatory authorities may disagree with our clinical trial protocol, which may delay or prevent us from initiating our clinical trials;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites, prospective CROs, and prospective local representatives which can be subject to extensive negotiation and may vary significantly among different local representatives, CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and
- The FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies or may impose other requirements before permitting us to initiate or complete a clinical trial.

Our product development costs will increase if we experience delays in clinical trials or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our products following approval and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

Even if we obtain regulatory approval of a product candidate, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory authorities in other countries continue to review and inspect marketed products, manufacturers, and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market or a withdrawal of the approved application by the FDA. Furthermore, FDA may require post-approval studies or other post-approval requirements or commitments. Failure to comply with or meet those requirements or commitments could result in withdrawal of the approved application by FDA. Regulatory authorities may also establish additional regulations, policies, or guidance that could prevent or delay regulatory approval of our product candidates.

We cannot market and sell our product candidates in the U.S. or in other countries if we fail to obtain the necessary regulatory approvals.

We cannot sell our product candidates until regulatory authorities grant marketing approval. The process of obtaining regulatory approval is lengthy, expensive, and uncertain, and the legal requirements for obtaining approval may change. It is likely to take several years to obtain the required regulatory approvals for our lead product candidates, or we may never gain the necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations. Moreover, because our product candidates are all based on only three platform technologies, any adverse events in any of our clinical trials for one of our product candidates could negatively impact the clinical trials and approval process for our other product candidates.

The pathway to regulatory approval for mesenchymal stem cells may be more complex and lengthier than for approval of a new conventional drug. Similarly, to obtain approval to market our cell products outside of the U.S., we, together with our collaborative partners, will need to file appropriate applications and submit clinical data concerning our product candidates and receive regulatory approval from governmental agencies, which in certain countries includes approval of the price we intend to charge for our product. We may encounter delays or rejections if changes occur in regulatory agency regulations, policies or guidance during the period in which we develop a product candidate or during the period required for review of any application for regulatory agency approval. If we are not able to obtain regulatory approvals for use of our product candidates under development, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business.

If we are not able to conduct our clinical trials properly and on schedule, marketing approval by 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 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, Current Good Clinical Practices (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 may be delayed or denied by the FDA.

Final marketing approval of our product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which could adversely affect our ability to generate operating revenues.

Final marketing approval for our product candidates may be delayed, limited, or denied if, among other factors:

- we are unable to satisfy the significant clinical testing required to demonstrate safety and effectiveness of our product candidates before marketing applications can be filed with the FDA or another regulatory authority;
- the FDA or other regulatory authorities do not agree with our interpretation of data obtained from preclinical and nonclinical animal testing or human clinical trials, even though the data can be interpreted in different ways;
- we fail at any stage of the development and testing of our product candidates, which may take years to complete;
- we receive negative or inconclusive results or reports of adverse side effects during a clinical trial;
- the FDA does not accept our application for filing;
- the FDA issues us a complete response letter during its review of our filed application; or
- the FDA requires us to expand the size and scope of the clinical trials or to conduct one or more additional trials.

If marketing approval for our product candidates is delayed, limited, or denied, our ability to market products, and our ability to generate product sales, could be adversely affected.

There has been very little success in gaining FDA approval for an Alzheimer's disease drug, and we have not had success to date in developing Alzheimer's disease therapeutics.

Despite billions of dollars invested by the biopharmaceutical industry in research programs to develop novel therapeutics for AD, there are few FDA-approved treatments. For example, Aduhelm® (aducanumab-avwa), an amyloid beta-directed antibody, was approved by FDA in June 2021 under FDA's accelerated approval pathway based upon the drug's effect on a surrogate endpoint. FDA has required confirmatory trials of clinical benefit, and there is ongoing public discussion of the drug's clinical benefit. Leqembi™ (lecanemab-irmb), also an amyloid beta-directed antibody, was approved in January 2023 under the accelerated approval pathway as well and will therefore likewise require confirmatory trials.

Many new types and classes of drugs have been developed and tested in AD, including monoclonal antibodies, g-secretase modulators and inhibitors, β-site amyloid precursor protein cleaving enzyme (BACE) inhibitors, receptor for advanced glycation end-products ("RAGE") inhibitors, nicotinic agonists, serotonin subtype receptor (5HT6) antagonists, and others. The vast majority of these scientific programs have failed in clinical testing. Moreover, we have not had any success to date in developing therapeutics for AD, and we may never do so.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our clinical trials. Specifically, the limited number of bone marrow transplant centers further heightens our dependence on such research institutions for our future Phase 3 clinical trials. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects and delays may occur which may result in our incurring additional costs. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is breached or terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Even if we do replace the institution, we may incur additional costs to conduct the trial at the new institution. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

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.

Even if we receive regulatory approval of Lomecel-B™ or any of our other 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 product candidates.

Any regulatory approvals that we receive for Lomecel-B™ 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 Risk Evaluation and Mitigation Strategy (REMS) program in order to approve our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use (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 product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our 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 product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate.

Later discovery of previously unknown problems with our 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 products, withdrawal of the 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 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 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.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

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 product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

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, 2021, 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.

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 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.

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 direct 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 has been 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.

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 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.

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.

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 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 product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Healthcare reform in the U.S. and other countries may materially and adversely affect us.

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.

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

Under the ACA, there are many programs and requirements for which details or consequences are still not fully understood. 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 approved products, reduce volumes of medical procedures or impose new cost-containment measures could adversely affect us.

Prescription Drug Pricing 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 modified.

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 product candidates. Any problems experienced by these third parties could result in a delay or interruption in the supply of our 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 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 product candidates. Any prolonged disruption in the operations of third parties could have a significant negative impact on our ability to produce our 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 product candidates or receive approval for any product candidates in a timely manner.

We currently depend upon third parties for services and raw materials needed for the manufacture of our 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 product candidates for use in clinical studies, and to produce any of our 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 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 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 product candidates with consistent characteristics. While we currently produce our 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 product candidates that are approved for commercial sale.

In addition, if one or more of our 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.

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

We may use a third-party manufacturer to supply our product candidates for clinical trials or other uses at some point. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the 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 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 product candidates, delays, suspensions, or withdrawals of approvals, license revocation, seizures or recalls of product candidates or our other products, operating restrictions, and criminal prosecutions. Any of these actions could significantly and adversely affect supplies of our product candidates or other 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 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 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 product candidates. As a result, our financial results and the commercial prospects for our 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.

If we decide 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 product candidates or 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 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 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 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.

The successful commercialization of our current or future 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 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 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 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 product candidates or products to other available therapies. Conducting one or more additional clinical trials would be expensive and could result in delays in commercialization of our product candidates.

Managing and reducing health care 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 products. In addition, payors are continuing to limit reimbursements for newly approved health care 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 product candidates and commercialize our 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 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 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.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products or product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership 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 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 merger or acquisition;
- 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 product candidates; and
- our inability to generate revenue from acquired technology, 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, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization

expense. Moreover, we may not be able to locate suitable acquisition opportunities, 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.

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 will comply with applicable healthcare laws and regulations will 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.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union (EU). The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements

relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Risks Related to the Discovery, Development and Commercialization of Our 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 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 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 product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or 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 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, Japanese PMDA 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 Lomecel-B™ 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 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 a product, comparable regulatory authorities in other foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product 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 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 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 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 product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about 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 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 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 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 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 a product candidate or continued marketing of an 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 an 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 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 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 a 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 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 Lomecel-B™ 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 Lomecel-B™ 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 Lomecel-B™ to treat HLHS. These designations were granted following our Phase 1 safety-focused ELPIS trial, However, even though the FDA has granted Lomecel-B™ 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. This voucher program has been extended in the past, but there is no guarantee the Congress will extend it again in the future.As of December 20, 2024, the rare pediatric disease PRV program has expired and PRVs may no longer be awarded unless the drug has already received a Rare Pediatric Disease Designation as of that date, and the application is approved no later than September 30, 2026. If we do receive a PRV upon approval of Lomecel-B™ 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 Lomecel-B™ 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 product candidates will receive marketing approval for this indication.

The FDA's Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations for Lomecel-B™ for mild AD does not guarantee that Lomecel-B 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.

FDA has granted two designations to Lomecel-B™ for the treatment of mild AD based on the completion of certain clinical trials: Regenerative Medicine Advanced Therapy (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 Lomecel-B™ 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 Lomecel-B™ 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 Lomecel-B™ 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.

Existing regulations and regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the 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.

For example, the ACA substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacted the U.S. pharmaceutical industry. Since its enactment, there have been judicial and Congressional

challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

Other legislative changes have been adopted since the ACA was enacted, including mandatory sequestration (e.g., aggregate reductions of Medicare payments to providers up to 2%), which will remain in effect through fiscal year 2031 absent additional Congressional action. Moreover, 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 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.

The Inflation Reduction Act of 2022, signed into law by former President Biden on August 16, 2022, contains several significant provisions regarding drug pricing, coverage, and reimbursement that could materially impact our business. Among the key provisions related to drug pricing, Title XI of the Social Security Act would be amended to direct the Secretary of the U.S. Department of Health and Human Services to establish a Drug Price Negotiation Program to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government for certain prescription drugs. Each year, under the Drug Price Negotiation Program, the Secretary would identify a small number of single-source brand name drugs or biologics, without generic or biosimilar competition, and for which certain periods of time have elapsed since drug approval, that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). These selected drugs would be subject to negotiation to establish a maximum fair price charged to Medicare. Manufacturers that are noncompliant with the drug price negotiation program would be subject to an excise tax and other civil monetary penalties during noncompliance periods. Other important drug pricing provisions include a mandatory rebate for drug manufacturers of certain Medicare Part B and Part D drugs with prices increasing faster than inflation; caps on annual out-of-pocket spending for Medicare beneficiaries; and limits of $35 for monthly cost-sharing for insulin products under Medicare Part D and a cap of 20% of the Medicare-approved amount after reaching the Medicare Part B deductible.

In addition, other legislative changes have been proposed and adopted in the U.S. that could impact our future business and operations, including those that may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our business, financial condition, and results of operations. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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.

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

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

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 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 market, sell and distribute our products for which we obtain marketing approval. Although our products 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. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- *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. A determination of liability under the Stark Law could have a material adverse effect on our business, financial condition and results of operations;
- *Federal Anti-Kickback Statute*. We will also be subject to the federal Anti-Kickback Statute if any of our 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. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties, criminal penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid. Imposition of any of these remedies could have a material adverse effect on our business, financial condition and results of operations, if in the future we provide services reimbursable by government healthcare programs.
- *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 and may provide the basis for exclusion from 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. 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.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- *Physician Payments Sunshine Act.* 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 starting in 2022 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; and
- *Other Healthcare Laws*. The FCA established several separate criminal penalties for making false or fraudulent claims to insurance companies and other non-governmental payers of healthcare services. Under FCA, 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. 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. 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 False Claims Act, which can impose additional penalties associated with the wrongful act. The routine waivers of copayments and deductibles offered to patients covered by commercial payers may also 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. Additionally, pharmaceutical and device manufacturers may be 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, including, without limitation, the Consumer Fraud Act, fee splitting, patient brokering, and other state and federal laws and regulations, as well as similar foreign laws in jurisdictions outside the U.S., where applicable involving various pharmaceutical regulation issues, fraud and abuse, price reporting, data privacy and security, and transparency.

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 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 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, and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. 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 product candidates in the future.

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

- our inability to design such 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 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 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 research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, or if the laws and regulations regarding animal testing otherwise change, our research and development activities may be interrupted, delayed or become more expensive.

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. It is additionally uncertain whether our employees, agents, or contractors, or those of our affiliates, would meet the requirements of any individualized exception to the FCPA enforcement moratorium imposed by President Trump's executive order. 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 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 products and technology, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our 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 products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our 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 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' 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 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 product candidate development programs or commercialization efforts.

The development of pharmaceutical drugs is capital intensive. We are currently advancing Lomecel-B™ into clinical development. Our current cash resources are insufficient to fund our planned operations or development plans beyond the fourth quarter of 2025, based on our current operating budget and cash flow forecast. 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 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 product candidates. As a result of our Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. Our operating expenses and capital expenditure requirements are expected to accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing/capital raises/non-dilutive funding options to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

In addition, if we obtain marketing approval for any of our current or future 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 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 product candidates, delay our pursuit of potential licenses or acquisitions, or significantly reduce our operations.

We expect that the net proceeds from recent offerings, together with our existing cash, will be sufficient to fund our operations into the fourth quarter of 2025. 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 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 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 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 product candidates.

Identifying potential current or future 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 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 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 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 or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Failure to maintain our share price above the minimum bid price requirement established by Nasdaq could result in the delisting of our Class A common stock on the Nasdaq Capital Market. The loss of our Nasdaq listing would in all likelihood make our Class A common stock significantly less liquid and adversely affect its value.

As of February 18, 2025 our Class A common stock closing bid price was $1.58. In January 2025, the SEC approved Nasdaq's proposal to modify its listing standards governing minimum bid price compliance periods and delisting processes, such that, among other matters, if a company fails to maintain a closing bid price of at least $1.00 per share (the "Minimum Bid Price Requirement"), and had previously executed a reverse stock split within the prior year, it would immediately receive a notification letter from the Nasdaq Listing Qualifications Department commencing delisting proceedings, with no compliance period. As previously disclosed, the Company undertook a reverse stock split on March 26, 2024. As such, if our Class A common stock closing bid price drops below $1.00 prior to March 26, 2025, we would be subjected to immediate delisting proceedings.

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 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.

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 (the "Board") 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. In particular, for so long as the Class B common stock remains outstanding, the holders may be able to cause or prevent a change of control of our Company or a change in the composition of our Board of Directors and could preclude any unsolicited acquisition of our Company. 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. As of February 17, 2025, three holders of our Class B common stock, Joshua M. Hare, co-founder, Chief Science Officer and Chairman of the Board of Directors, Donald M. Soffer, co-founder and former member of our Board of Directors, and Rock Soffer, member of our Board of Directors, control voting rights over approximately 37% of the combined voting power of our Class A common stock and Class B common stock.

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 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 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. As of February 17, 2025, we had an aggregate of 84,295,000 shares of Class A common stock authorized and of that approximately 62,902,003 not issued, outstanding or reserved for issuance (for purposes of warrant exercise or under the Company's current Second Amended and Restated 2021 Incentive Award Plan). 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 a 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 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 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.

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 transition into 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 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 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 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 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 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 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. Under the current Tax Act, 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 product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our 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 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 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, product candidates or future approved products. Finally, social media may aid in the social reform of current drug prices. For example, CVS's recently proposed "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"), other members of management and relevant management committees, including 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.

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, 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 ("vCIO") 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 or 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.

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 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 February 17, 2025, there were 19 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, 13,473,898 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 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, 2024	27,620	$ 1.88	-	-
November 1-30, 2024	233	1.98	-	-
December 1-31, 2024	-	-	-	-
Total	27,853	$ 1.88	-	-

(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. The Company's lead investigational product is Lomecel-B™. Lomecel-B™ has multiple modes of action that include pro-vascular, pro-regenerative, and anti-inflammatory mechanisms, promoting tissue repair and healing with broad potential applications across a spectrum of disease areas.

We are currently pursuing three pipeline indications: Hypoplastic Left Heart Syndrome ("HLHS"), Alzheimer's disease ("AD") and Aging-related Frailty. Our mission is to advance Lomecel-B™ and other cell-based product candidates into pivotal or Phase 3 trials, with the goal of achieving regulatory approvals, subsequent commercialization, and broad use by the healthcare community.

Financial Overview. 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 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 has incurred recurring losses from operations since its inception, and as of December 31, 2024 the Company had an accumulated deficit of $109.6 million. The Company expects to continue to generate operating losses for the foreseeable future.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025 based on our current operating budget and cash flow forecast. However, as a result of our Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. Our operating expenses and capital expenditure requirements are expected to accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing/capital raises/non-dilutive funding options 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 we will be able to attain future financing at terms favorable to us or at all.

Operational Overview. With respect to HLHS, we are exploring the possibility that Lomecel-B™ when administered directly to the myocardium of affected infants, can improve outcomes in this devastating rare pediatric disease. The standard of care in HLHS is a series of three heart surgeries (staged surgical palliation) that reconfigures the single right ventricle to support system circulation. Despite these life-saving surgical interventions, it is estimated that only 50 to 60 percent of affected individuals survive until adolescence. The pro-vascular, pro-regenerative and anti-inflammatory properties of Lomecel-B™ may improve the function of the right ventricle in these infants. A previous Longeveron Phase 1 open-label study indicated that such a benefit may exist when outcomes were compared to historical controls. Longeveron is currently conducting a controlled study to determine the actual benefit of Lomecel-B™ in these patients.

As of February 17, 2025, we have completed five U.S. clinical studies of Lomecel-B™: Phase 1 AD, Phase 1 HLHS, Phase 1/2 Aging-related Frailty ("HERA Trial"), Phase 2a AD (CLEAR MIND Trial"), and Phase 2b Aging-related Frailty. We currently have one clinical trial actively enrolling patients: Phase 2b HLHS ("ELPIS II" trial). Additionally, we sponsor a registry in The Bahamas under the approval and authority of the National Stem Cell Ethics Committee. The Bahamas Registry Trials may administer Lomecel-B™ to eligible participants at private clinics in Nassau for a variety of indications. While Lomecel-B™ 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.

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 cGMP manufacturing facility with research and development labs, business planning, raising capital, establishing 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.

We manufacture all of our own product candidates for clinical trials. In 2017 we opened a manufacturing facility comprised of eight clean rooms, two research and development laboratories, and warehouse and storage space. We have supply contracts with multiple third parties for fresh bone marrow, which we use to produce our 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.

Since the time that we became a publicly traded company in February 2021, we have sold 12,686,240 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, 2024, warrants exercisable for an aggregate of up to 6,802,668 shares of a Company's Class A common stock remain outstanding at exercise prices ranging from $2.35 per share to $175.00 per share.

When appropriate funding opportunities arise, we routinely apply for grant funding to support our ongoing research and since 2016 we have received approximately $16.0 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.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based upon our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, (U.S. GAAP). The preparation of these financial statements requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. We base our estimates on historical experience, anticipated results and trends and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily available from other sources. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty, and management evaluates them on an ongoing basis for changes in facts and circumstances. Changes in estimates are recorded in the period in which they become known. Actual results may differ from our estimates under different assumptions or conditions. While our significant accounting policies and estimates are described in more detail in the accompanying Notes to the Condensed Financial Statements contained in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical due to the judgments and estimates used in the preparation of our financial statements.

Revenue recognition.

We recognize revenue associated with our contract manufacturing services, which may require us to exercise considerable judgment in estimating revenue to be recognized, including judgments made on day one accounting and judgments associated with the amount of revenue to be recognized over time as performance obligations are satisfied.

Significant judgment is required to apply the authoritative accounting guidance at the outset of our contract manufacturing services agreement, and over time, as detailed below:

Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require judgment. For our contract manufacturing services revenue, the contract generally includes the terms of the contract manufacturing services and related ancillary services or procedures to comply with regulatory requirements. We have determined, our performance obligations vary per contract and are accounted for as separate performance obligations when a product or services is delivered. If a product or service is determined not to be delivered as in the case of an initial down payment that amount is deferred and combined with another related performance obligation. If a contract contains a single performance obligation, we allocate the entire transaction price to the single performance obligation. If a contract contains multiple performance obligations, we allocate consideration to each performance obligation using the “relative standalone selling price”. Generally, we utilize observable standalone selling prices in our allocations of consideration. If observable standalone selling prices are not available, we estimate the applicable standalone selling price using a cost-plus-margin approach or an adjusted market assessment approach, in each case, representing the amount that we believe the market is willing to pay for the applicable service or product. Revenue is recognized over time using an appropriate method of measuring progress towards

fulfilling our performance obligation for the respective arrangement. Determining the measure of progress that consistently depicts our satisfaction of performance obligations within each of our revenue streams across similar arrangements requires judgment.

The identified performance obligations will impact most significantly the timing of revenue recognition, and is either at a point in time or an over-time mainly based transfer of control assessment performed at the outset of the arrangement.

For revenue recognized over time, this is based on an underlying measure deemed to approximate the progress towards satisfaction of performance obligations for the respective arrangement. These underlying measures, such as costs incurred to date compared with total forecasted costs for a service, may include inherent estimates, which in turn can impact the timing of revenue recognition. For revenue recognized at a point in time, revenue is recognized once the performance obligation is satisfied, meaning the product is delivered or the service is completed, signifying the transfer of control at a specific point in time, The satisfaction of performance obligations assessment is performed at each reporting period. To date, there have been no material true ups to revenue as a result of changes in the satisfaction of performance obligations.

Going Concern Assessment

The Company has recently faced significant losses over the previous years and expects to incur losses for the foreseeable future. As a result, the company's management has conducted an assessment of its financial condition, including cash flow projections for the next twelve months from the date the financial statements will be issued. Based on this assessment, management has identified potential material uncertainties that could cast substantial doubt on the company's ability to continue as a going concern. This assessment includes significant assumptions and estimation of uses and forecasts of cash flows in future periods.

To address these uncertainties, management has developed a plan that includes among other things the potential for securing additional financing and non-dilutive funding such as grants. Cost reductions would also be evaluated if needed. The successful execution of these plans is contingent upon various factors some of which may be outside the Company's control.

Given the significant judgment and subjectivity of these estimates involved in assessing the feasibility of these plans and their potential impact on future cash flows, management considers the going concern assessment to be a critical accounting estimate. The financial statements include a disclosure outlining the nature of these uncertainties, the assumptions made by management, and the potential impact on the company's financial position and performance.

Components of Our Results of Operations

Revenue

We have generated revenue from three sources:

- **The Bahamas Registry Trials**. Participants in The Bahamas Registry Trial pay us a fee to receive Lomecel-B™, imported into The Bahamas, and administered at one of two private medical clinics in Nassau. While Lomecel-B™ is considered an investigational product in The Bahamas, under the approval terms received from the National Stem Cell Ethics Committee, we are permitted to charge a fee for participation in the Registry Trial. The fee is recognized as revenue and is used to pay for the costs associated with manufacturing and testing of Lomecel-B™, 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. Lomecel-B™ is considered an investigational treatment in The Bahamas and is not licensed for commercial sale.
- **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.
- **Grant awards.** Extramural grant award funding, which is non-dilutive, has been a core strategy for supporting our ongoing clinical research. Since 2016 our clinical programs have received over $16.0 million in competitive extramural grant awards ($11.5 million which has been directly awarded to us and which are recognized as revenue when the performance obligations are met) from the NIH, Alzheimer's Association, and MSCRF.

Cost of Revenues

We record cost of revenues based on expenses directly related to revenue. For grants we record allocated expenses for research and development costs to a grant as a cost of revenues. 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 include costs such as clinical trial expenses, contracted research and 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 contract research organizations ("CROs") and 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 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 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.

We expect that our research and development expenses will continue to be significant in the future as we increase our headcount to 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 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; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Other Income and Expenses

Interest income consists of interest earned on cash equivalents and marketable securities. The increase in interest income for the current year was primarily driven by a higher balance of cash compared to the prior year.

No provision for income taxes has been recorded for the years ended December 31, 2024 and 2023. We may incur income taxes in the future if we have earnings. At this time the Company has not evaluated the impact of any future profits.

RESULTS OF OPERATIONS

COMPARISON OF THE YEARS ENDED DECEMBER 31, 2024 AND 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023, together with the changes in those items in dollars (in thousands):

	Year Ended December 31,		Increase (Decrease)
	2024	2023	
Revenues	$ 2,392	$ 709	$ 1,683
Cost of revenues	508	488	20
Gross profit	1,884	221	1,663
Operating Expenses			
General and administrative	10,269	12,184	(1,915)
Research and development	8,137	9,066	(929)
Total operating expenses	18,406	21,250	(2,844)
Loss from operations	(16,522)	(21,029)	(4,507)
Other income and (expense)			
Lawsuit expense	-	(30)	(30)
Other tax credits	-	23	(23)
Other income (expense), net	549	(377)	926
Total other income (expenses), net	549	(384)	933
Net loss	$ (15,973)	$ (21,413)	$ (5,440)

Revenues, Cost of Revenues and Gross Profit: Revenues for the years ended December 31, 2024 and 2023 were $2.4 million and $0.7 million, respectively. 2024 revenues increased $1.7 million, or 237%, when compared to 2023 as a result of higher participant demand for our Bahamas Registry Trial and the addition of our manufacturing services contract. Clinical trial revenue, which is derived from the Bahamas Registry Trial, for the years ended December 31, 2024 and 2023 was $1.4 million and $0.7 million, respectively, reflecting an increase of $0.7 million, or 110%, when compared to 2023 as a result of increased participant demand. Contract manufacturing revenue for the year ended December 31, 2024 was $1.0 million, consisting of $0.5 million from our manufacturing lease services and $0.5 million from our manufacturing services contract.

Related cost of revenues was $0.5 million and $0.5 million for the years ended December 31, 2024 and 2023, respectively. This resulted in a gross profit of approximately $1.9 million for the year ended December 31, 2024, an increase of $1.7 million, or 752%, when compared with a gross profit of $0.2 million for 2023.

General and Administrative Expense: General and administrative expenses for the year ended December 31, 2024 decreased to approximately $10.3 million compared to $12.2 million for the same period in 2023. The decrease of approximately $1.9 million, or 16%, was primarily due to lower personnel expenses as a result of reduced severance in 2024 and lower legal and other administrative expenses.

Research and Development Expenses: Research and development expenses for the year ended December 31, 2024 decreased to approximately $8.1 million from approximately $9.1 million for the same period in 2023. This decrease of $1.0 million, or 10%, was primarily driven by a reduction of $2.3 million in expenses related to the completed CLEAR MIND Alzheimer's disease clinical trial, reduced costs for the Aging-related Frailty clinical trial following our decision to discontinue trial activities in Japan, and a $0.9 million decrease in supply costs. These reductions were partially offset by $1.7 million in higher compensation and benefit costs and a $0.3 million increase in equity-based compensation expenses allocated to research and development.

Research and development expenses consisted primarily of the following items (less those expenses allocated to the cost of revenues) (in thousands):

	Year Ended December 31,	
	2024	2023
Clinical trial expenses-statistics, monitoring, labs, sites, etc.	$ 2,031	$ 4,349
Supplies and costs to manufacture Lomecel-B™	327	1,214
Employee compensation and benefits	3,554	1,861
Equity-based compensation	825	555
Depreciation	735	722
Amortization	224	224
Travel	173	38
Other activities	268	103
Total	$ 8,137	$ 9,066

Other Income (Expense), net: Other income (expense) for the years ended December 31, 2024 and 2023 was an income of $0.6 million and an expense of $0.4 million, respectively. Net other income for 2024 was driven by a higher interest income, compared to net other expense for 2023 driven by realized losses on sales of marketable securities of $0.3 million, write-offs of intangible assets of $0.3 million and reduced benefit of tax credits of $0.3 million.

Net Loss: Net loss decreased to approximately $16.0 million for the year ended December 31, 2024 from a net loss of $21.4 million for the same period in 2023. The decrease in the net loss of $5.4 million, or 25%, 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,	
	2024	2023
Net cash used in operating activities	$ (13,868)	$ (19,002)
Net cash (used in) provided by investing activities	(640)	8,186
Net cash provided by financing activities	28,791	5,262
Net increase (decrease) in cash and cash equivalents	$ 14,283	$ (5,554)

Operating Activities. We have incurred losses since inception. 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 for 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. Net cash used in operating activities for the year ended December 31, 2023 was $19.0 million, consisting primarily of our net loss of $21.4 million and payments for accounts payable of $1.1 million and payment of the non-operating lawsuit of $1.4 million. This was partially offset by non-cash expenses of $2.0 million in equity-based compensation expenses, $0.9 million in depreciation and amortization, and $0.3 million for the write-off of intangible assets, as well as an increase in accrued expenses of $1.5 million.

Investing Activities. Net cash used in investing activities for the year ended December 31, 2024 was $0.6 million consisting primarily of additions to intangible assets of $0.6 million and purchases of equipment of $0.3 million, which was partially offset by proceeds from the sale of marketable securities of $0.3 million. Net cash provided by investing activities for year ended December 31, 2023 was $8.2 million consisting primarily of proceeds from the sale of marketable securities of $8.9 million, which was partially offset by additions to intangible assets of $0.4 million and purchases of equipment of $0.3 million.

Financing Activities. 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. Net cash provided by financing activities for the year ended December 31, 2023 was $5.3 million consisting primarily of $5.4 million of net proceeds received from the October 2023 and December 2023 offerings.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have incurred significant operating losses. 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 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, and fees generated from the Bahamas Registry Trials and contract manufacturing services. Since we were formed, we have raised approximately $113.0 million in gross proceeds from the issuance of equity. As of December 31, 2024, the Company had cash and cash equivalents of $19.2 million and working capital of approximately $17.0 million.

We currently believe that our cash and cash equivalents as of December 31, 2024 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025 based on our current operating budget and cash flow forecast. However, as a result of our successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. Our operating expenses and capital expenditure requirements are expected to accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing and non-dilutive funding options to support these activities, and the current cash projections may be impacted by these ramped up activities and any financing transactions entered into. There can be no assurance we will be able to attain future financing at terms favorable to us or at all.

Capital Raising Efforts

Since the time that we became a publicly traded company in February 2021, we have sold 12,686,240 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, 2024, warrants exercisable for an aggregate of up to 6,802,668 shares of a Company's Class A common stock remain outstanding at exercise prices ranging from $2.35 per share to $175.00 per share.

On April 8, 2024, the Company commenced a public offering of up to 639,872 shares of the Company’s Class A common stock, along with pre-funded warrants to purchase up to an aggregate 1,572,894 shares of Class A common stock (the “Pre-Funded Warrants”). The shares and Pre-Funded Warrants were sold together with warrants to purchase up to an aggregate of 2,212,766 shares of Class A common stock (the “Common Warrants”). The combined public offering price was $2.35 per share and related Common Warrant and $2.349 per Pre-Funded Warrant and related Common Warrant. Subject to certain limitations, the Pre-Funded Warrants were immediately exercisable and could be exercised at a nominal consideration of $0.001 per share of Class A common stock at any time until all of the Pre-Funded Warrants were exercised in full. The Common Warrants were immediately exercisable and expire on April 10, 2029.

As compensation to the placement agent the Company also issued to designees of the placement agent warrants to purchase up to 154,894 shares of Class A common stock, which had substantially the same terms as the Common Warrants, and with an exercise price of $2.9375 per share and a term of five years from the commencement of sales in the offering.

In connection with the offering, the Company also entered into an agreement with a holder of existing warrants to amend the holder’s existing Series A warrants and Series B warrants that were issued in a private placement as part of the Company's October 2023 registered direct offering to reduce the exercise price to $2.35 per share and (ii) amend the expiration date of the Series A Warrants to five and one-half (5.5) years following the closing of the public offering and the Series B warrants to eighteen (18) months following the closing of the public offering, in each case for a payment to the Company of $0.125 per amended warrant.

On April 16, 2024, the Company entered into inducement letter agreements with certain holders of its existing Series A warrants and Series B warrants, and Common Warrants issued on April 10, 2024, whereby the holders agreed to exercise the warrants for cash at the exercise price of $2.35 per share in consideration for payment of $0.125 per new warrant and for the Company’s agreement to issue new unregistered Class A common stock warrants to purchase up to 4,799,488 shares of Class A common stock at an exercise price of $2.35 per share, and which were immediately exercisable upon issuance. The warrants to purchase up to 2,399,744 shares of Class A common stock (the “Series C Warrants”) have a term of five (5) years from the issuance date, and

the warrants to purchase up to 2,399,744 shares of Class A common stock (the “Series D Warrants”) have a term of twenty-four (24) months from the issuance date, with all of the Series C Warrants and Series D Warrants being immediately exercisable. All of the Series D Warrants were exercised in June 2024, pursuant to ordinary course exercise as well as a subsequent inducement transaction.

Additionally, the Company issued to the placement agent or its designees as compensation, warrants to purchase up to 167,982 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued upon exercise of the warrants pursuant to the inducement transaction, which had the same terms as the Series C Warrants, except that the placement agent warrants have an exercise price of $3.25 per share.

Furthermore, upon exercise, if any, of the Series D Warrants for cash, the Company agreed to issue the placement agent or its designees, within five (5) business days of the Company’s receipt of the exercise price, warrants to purchase the number of shares of Class A common stock equal to 7.0% of the aggregate number of shares underlying such Series D Warrants that have been exercised, with such warrants to be in the same form and terms as the prior placement agent warrants.

On April 18, 2024, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-278995) registering the resale of an aggregate of 4,967,470 shares of Class A common stock issuable upon exercise of certain warrants, including (i) up to 2,399,744 shares issuable upon the exercise of the Series C Warrants issued in the April 2024 warrant inducement transaction; (ii) up to 2,399,744 shares issuable upon the exercise of the Series D Warrants issued in the April 2024 warrant inducement transaction; and (iii) up to 167,982 shares issuable upon exercise of the warrants issued to the placement agent or its designees in the April 2024 warrant inducement transaction. The Form S-1 was subsequently amended by the Company and declared effective by the SEC on May 21, 2024.

On June 17, 2024, the Company entered into additional inducement letter agreements with the holders of its existing Series D Warrants to exercise the remaining 1,697,891 shares of Class A common stock underlying Series D Warrants that remained outstanding for cash at the exercise price of $2.35 per share in consideration for the Company’s agreement to issue new unregistered Class A common stock warrants (the "June Inducement Warrants"), for payment of $0.125 per new warrant, to purchase up to an aggregate of 3,395,782 shares of Class A common stock at an exercise price of $2.50 per share and which were immediately exercisable upon issuance and have a term of twenty-four (24) months from the issuance date.

The Company also issued to the placement agent or its designees as compensation, (i) warrants to purchase up to 118,852 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued upon exercise of the warrants pursuant to the June inducement transaction and (ii) warrants to purchase up to an aggregate of 49,130 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Common Stock issued upon exercise of certain Series D warrants prior to the inducement transaction, which had substantially the same terms as the June Inducement Warrants, except that the warrants exercisable for 118,852 shares had an exercise price of $3.25 per share and the warrants exercisable for 49,130 shares had an exercise price $2.9375 per share, respectively (collectively, the "June placement agent warrants").

Upon exercise, if any, of the June Inducement Warrants for cash, the Company agreed to issue within five (5) business days to the placement agent or its designees, warrants to purchase the number of shares of Class A common stock equal to 7.0% of the aggregate number of shares of Class A common stock underlying such June Inducement Warrants that have been exercised, with such warrants to be in the same form and terms as the June placement agent warrants.

The issuance under the inducement offers represented $8.5 million in additional value provided to the investors, which was recorded as a deemed dividend to common stockholders. The June Inducement Warrants expire on June 18, 2026.

On June 28, 2024, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-280577) registering the resale of an aggregate of 3,563,764 shares of Class A common stock issuable upon exercise of certain warrants, including (i) up to 3,395,782 shares issuable upon the exercise of the June Inducement Warrants and (ii) up to 167,982 shares issuable upon the exercise of the June placement agent warrants. The Form S-1 was subsequently declared effective by the SEC on July 9, 2024.

On July 10, 2024, a holder exercised Series C warrants for 50,000 shares of Class A common stock for cash (the “July Series C warrant exercise”).

On July 10, 2024, certain holders of warrants issued in June of 2024 exercised warrants to purchase an aggregate of 150,000 shares of Class A common stock for cash (the “July 10 warrant exercise”). In addition, on July 17, 2024, we issued to the placement agent warrants to purchase up to 10,500 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued in the July 10 warrant exercise (the “first tranche July ordinary course placement agent warrants”). The first tranche July ordinary course placement agent warrants have substantially the same terms as the June

placement agent warrants, except that the first tranche July ordinary course placement agent warrants (i) have an exercise price of $3.125 per share and (ii) expire July 17, 2026.

On July 17, 2024, a holder of the June Inducement Warrants exercised the same to purchase 2,319,186 shares of Class A common stock for cash (the “July 17 warrant exercise” and together with the July 10 warrant exercise and the July Series C warrant exercise, collectively, the “July warrant exercises”). Accordingly, on July 24, 2024, we issued to the placement agent warrants to purchase up to 162,344 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued in the July 17 warrant exercise (the “second tranche July ordinary course placement agent warrants”, and together with the first tranche July ordinary course placement agent warrants, the “July ordinary course placement agent warrants”, and collectively with the July offering placement agent warrants, the “July placement agent warrants”). The second tranche July ordinary course placement agent warrants have substantially the same terms as the first tranche July ordinary course placement agent warrants, except that the second tranche July ordinary course placement agent warrants expire July 24, 2026.

The gross proceeds to the Company from the July warrant exercises, inclusive of the payment consideration for such Series C warrants and June Inducement Warrants, were approximately $6.3 million, inclusive of the payment consideration for such warrants, before deducting placement agent fees payable by the Company.

On July 18, 2024, we entered into a securities purchase agreement with institutional and accredited investors relating to the registered direct offering and sale of an aggregate of 2,236,026 shares of our Class A common stock at a purchase price of $4.025 per share of Class A common stock and associated warrant (the “July registered direct offering”). The securities issued in the July registered direct offering were offered pursuant to a prospectus supplement, dated July 18, 2024, and accompanying prospectus, in connection with a takedown from our shelf registration statement on Form S-3 (File No. 333-264142), which was declared effective by the SEC on April 14, 2022.

In a concurrent private placement (the “July private placement” and together with the July registered direct offering, the “July offering”), we also sold unregistered Class A common stock warrants to purchase up to an aggregate of 2,236,026 shares of our Class A common stock (the “July private placement warrants”). The unregistered July private placement warrants have an exercise price of $3.90 per share, became exercisable on July 19, 2024, and expire on July 20, 2026. In addition, the Company granted the placement agent warrants, under similar terms, to purchase 156,522 shares of Class A common stock, at an exercise price of $5.0313 (the “July offering placement agent warrants”). The gross proceeds to the Company from the July offering were approximately $9.0 million, before deducting placement agent fees and other offering expenses payable by the Company.

On August 6, 2024, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-281299) registering the resale of an aggregate of 2,565,392 shares of Class A common stock issuable upon exercise of certain warrants, of which (i) up to 2,236,026 shares are issuable upon the exercise of the July private placement warrants issued to the purchasers upon the closing of the July private placement; (ii) 156,522 shares are issuable upon exercise of the July offering placement agent warrants issued to Wainwright, or its designees, pursuant to the terms of the current engagement Letter with Wainwright; and (iii) 172,844 shares are issuable upon exercise of the July ordinary course placement agent warrants issued to Wainwright, or its designees, pursuant to the terms of a then-applicable engagement letter with Wainwright, in connection with previously exercised June Inducement Warrants. The Form S-1 was declared effective by the SEC on August 12, 2024.

In September 2024, the Company entered into additional inducement letter agreements with certain holders of its existing purchaser warrants issued as part of the Company’s 2021 private placement offering (the "Purchaser Warrants") to amend and reduce the exercise price of the Purchaser Warrants to $1.00 per share in consideration for the holders’ cash exercise of all Purchaser Warrants held by such holder on or before September 27, 2024. In connection with the September 2024 inducement transaction, Purchaser Warrants were exercised for 114,077 shares of Class A common stock, resulting in gross proceeds to the Company of $114,077. In October 2024, the Company entered into additional inducement letter agreements with the remaining holders of its existing Purchaser Warrants issued as part of the Company’s 2021 private placement offering to amend and reduce the exercise price of the Purchaser Warrants to $1.00 per share in consideration for the holders’ cash exercise of all Purchaser Warrants held by such holder. In connection with the October 2024 inducement transaction, Purchaser Warrants were exercised for 2,858 shares of Class A common stock. As of the date of this 10-K, the Purchaser Warrants have been exercised in full.

Grant Awards

From inception through December 31, 2024, we have been awarded approximately $11.9 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. As of December 31, 2024, and 2023, the amount of unused grant funds that were available for us to draw was approximately $0.1 million 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	Ongoing
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 Lomecel-B™. The total award was $4.6 million, and we have received $0.3 million of the approximately $0.5 million apportioned to us.

Terms and Conditions of Grant Awards

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.

Grant awards arise from submitting detailed research proposals to granting agencies 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

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 and our administrative overhead with the use of grant funding.

Specifically, we will incur expenses to:

- advance the clinical development of Lomecel-B™ for the treatment of several disease states and indications;
- pursue the preclinical and clinical development of other current and future research programs and product candidates;
- in-license or acquire the rights to other products, 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 product candidates that successfully complete clinical development; and
- optimize our operational, financial and management systems and increase personnel, including personnel to support our operations as a public company.

We currently believe that our cash and cash equivalents as of December 31, 2024 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025 based on our current operating budget and cash flow forecast. However, as a result of our successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as the Company currently anticipates a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. Our operating expenses and capital expenditure requirements are expected to accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase our current proposed spend and further increase its capital investments. We intend to seek additional financing/capital raises/non-dilutive funding options 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 we will be able to attain future financing at terms favorable to us or at all.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our 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 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, 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 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 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 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, 2024, we have $1.4 million in operating lease obligations and no CRO payment obligations. We 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 $1.07 billion or more, (2) the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (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 $19.2 million as of December 31, 2024. 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 December 31, 2024. 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. However, we do believe we can design and maintain more effective controls in 2025. These may include additions to personnel and or consultants; and formalizing and improving our accounting policies, procedures and controls.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, 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, Marcum LLP 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, 2024 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, 2024. 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, 2024, 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, 2024, But Not Reported

None.

Insider Trading Policies and Procedures

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, prohibits 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.

Trading Arrangements

None of the Company's directors or "officers," as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended (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, 2024.

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 (the "Board") and executive officers. The ages of individuals are provided as of February 1, 2025:

Name	Age	Position
Executive Officers		
Wa'el Hashad	62	Chief Executive Officer and Director
Joshua M. Hare, M.D.	62	Co-Founder, Chief Science Officer, Chairman and Director
Lisa Locklear	64	Chief Financial Officer and Treasurer
Paul Lehr, J.D.	57	General Counsel, and Secretary
Nataliya Agafonova	55	Chief Medical Officer
Non-Executive Employees		
Devin Blass	39	Chief Technology Officer and Senior Vice President of Chemistry, Manufacturing, and Controls
Non-Employee Directors		
Khoso Baluch	67	Director
Roger Hajjar, M.D.	60	Director
Richard Kender, M.D.	69	Director
Neha Motwani	48	Director
Rock Soffer	43	Director
Ursula Ungaro, J.D.	74	Director

Executive Officers

Wa'el Hashad, **M.B.A., (Chief Executive Officer ("CEO"))** was appointed in February 2023 as CEO of Longeveron Inc. Prior to this position, Mr. Hashad served as the President and CEO of Avanir Pharmaceuticals from 2017 until 2023. Prior to 2017, he served as the chairman of the strategic advisory board for Morningside Biopharma, a private incubator of several pharmaceutical/bio-tech companies, for three years. In addition, he has held vice president roles at Amgen Inc., Boehringer Ingelheim, and Eli Lilly and Company. Mr. Hashad earned an executive degree from the Wharton Business School, University of Pennsylvania, an M.B.A. degree from the University of Akron, and a Bachelor of Science degree from the University of Cairo.

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A. (Co-Founder, Chief Science Officer and Chairman) co-founded Longeveron in 2014 and has served on its Board of Directors and as its Chief Science Officer since that time. 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 to 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 serves on several philanthropic boards. She currently chairs the Board of Governors of the Gemological Institute of America and serves on the boards of Pacific Marine Mammal

Center and the Orange County United Way, and is a member of the National Association of Corporate Directors. She holds and Bachelor of Science degree in plant science from the University of California, Davis, and an M.B.A. degree 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 and 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.

Non-Executive Employees

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 severed 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

Khoso Baluch, was elected to Longeveron's Board of Directors in June 2023. Mr. Baluch has over 36 years of experience across global geographies in the biopharmaceutical industry. Since 2012, he has served as an independent director of Poxel S.A., a French publicly traded biotech company, chairs its compensation committee and as of March 2023 became Chairman. He also currently serves as an independent director of Processa Pharmaceuticals, Inc (NASDAQ: PCSA), and serves on its audit and compensation committees. He served as the Chairman of the Board for Da Volterra, a French privately held company, from December 2021 until November 2022. From 2016 to 2021, Mr. Baluch served as the Chief Executive Officer and Board member of CorMedix, Inc., a publicly traded pharmaceutical company in the United States. Mr. Baluch also held various senior positions at UCB, S.A. between January 2008 to April 2016, including Senior Vice President and President Europe, Middle East & Africa. Prior to joining UCB, Mr. Baluch worked for Eli Lilly and Company (NYSE: LLY) for 24 years, holding international positions spanning Europe, the Middle East and the United States in general management, business development, market access and product leadership. Mr. Baluch holds a B.S. in Aeronautical Engineering from City University London and an M.B.A. from Cranfield School of Management.

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 Atamayo Therapeutics. 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, MA. Dr. Hajjar earned his B.S. in Biomedical Engineering from Johns Hopkins University and his M.D. from Harvard Medical School.

Richard Kender was appointed to Longeveron's Board of Directors in May 2024. Mr. Kender is a 35-year veteran in the pharmaceutical industry and spent his entire career at Merck & Co., Inc. ("Merck") in the U.S. Rich worked in various corporate areas in the company, including Vice President of Corporate Development, Sr. Vice President and head of Merck's M&A, Licensing, Financial Evaluation and Analysis and Global Competitive Intelligence. During his tenure he was actively involved in more than 100 transactions of various sizes and transaction types. He was most recently the Senior Vice President of Business Development and Corporate Licensing, before retiring from Merck in September 2013. Mr. Kender currently serves on the Board of Directors of Seres Therapeutics (NASDAQ: MCRB) in Cambridge, Massachusetts, and serves as the Chair of the Audit Committee and is a member of the Compensation Committee; POXEL SA (Euronext: POXEL), in Lyon, France and serves as the Chair of the Business Development Committee and is a member of the Audit Committee and the Chair of the Compensation Committee; and Bicycle Therapeutics (NASDAQ: BCYC) in Cambridge, United Kingdom and Cambridge, Massachusetts, and serves as the Chair of the Audit Committee and is a member of the Strategic Committee and member of the Compensation Committee. Mr. Kender holds a B.S. Degree in Accounting from Villanova University and an M.B.A. from Fairleigh Dickinson University.

Neha Motwani was elected to Longeveron's Board of Directors in July 2024 and has over 25 years of healthcare investment banking experience. Most recently, she served as Managing Director, Health Care Investment Banking at William Blair from 2021 to 2023. From 2017 to 2021 Ms. Motwani served as the Managing Director, Health Care Investment Banking at Truist Securities. She previously held investment banking roles of increasing responsibility with Oppenheimer and Company, Stifel Financial and Cowen and Company, where, collectively, she completed transactions raising over $6.8 billion. Ms. Motwani earned her B.A. in political science from Columbia University.

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 currently serves as partner of the law firm Boies Schiller Flexner LLP. 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 after being nominated by President George H.W. Bush and being 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 the ORT Jurisprudence Award 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.

There are no family relationships among our current directors or executive officers. Rock Soffer is the son of an investor in the Company who owns approximately 4.5% of total shares outstanding as of February 17, 2025.

Board Composition and Election of Directors

Our Board currently consists of eight members. 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. 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 I director is Rock Soffer, and his term will expire at our annual meeting of stockholders to occur in 2025;
- the Class II directors are Wa'el Hashad, Khoso Baluch and Richard Kender, and their terms will expire at our annual meeting of stockholders to occur in 2026; and
- the Class III directors are Joshua M. Hare, Ursula Ungaro, Roger Hajjar, and Neha Motwani and their terms will expire at the annual meeting of stockholders to occur in 2027.

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 nine (9) meetings during 2024. Each director attended either in person or via teleconference at least 75% of the aggregate of all Board and applicable committee meetings during fiscal 2024 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. Two members of our Board were in attendance at our 2024 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: Mr. Baluch (chair), Mr. Kender and Ms. Motwani. 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. Mr. Baluch is the Audit Committee Chair, and the Board has determined that Mr. Kender qualifies as an audit committee financial expert, as that term is described in SEC regulations. The Audit Committee held four (4) meetings during 2024.

Compensation Committee. The Compensation Committee is comprised of three members: Ms. Ungaro (chair), Mr. Baluch and Mr. Kender. 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 of Directors 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'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 2024. 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 six (6) meetings during 2024.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee is comprised of three members: Dr. Hajjar(chair), Ms. Motwani, and Ms. Ungaro. 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 of directors. 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 2024.

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 of Directors by a stockholder.

Science and Strategy Committee. The Science and Strategy Committee is comprised of three members: Dr. Hajjar (chair), Dr. Hare, and Mr. Kender. 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 of Directors has adopted and approved a written charter for the Science and Strategy Committee. As a newly formed committee, no meetings of the Science and Strategy Committee were held in 2024.

Board Member Independence

The Board of Directors has determined that each of Dr. Hajjar, Mr. Kender, Ms. Motwani, Ms. Ungaro, and Mr. Baluch are independent as defined in the Nasdaq Stock Market listing standards and applicable SEC regulations. Dr. Hare and Messrs. Soffer, and Hashad 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, 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 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 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 of Directors 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 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).

Compensation Committee Interlocks and Insider Participation

No members of our Compensation Committee have ever been a current or former officer or employee. None of our executive officers serves or has served as a member of the Board of directors or a compensation committee (or other committee serving an equivalent function) of any entity that has one or more of its executive officer serving as one of our directors or on our Compensation Committee.

Delinquent Section 16(a) Reports

The Company's directors and executive officers are required under Section 16(a) of the Securities Exchange Act of 1934, as amended (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 2024 with the reporting requirements of Section 16(a) of the Exchange Act, with the exception of the following: (i) a Form 4 filed on January 25, 2024 reporting 3,074 shares withheld to satisfy tax obligations in connection with vesting of restricted stock award units by Nataliya Agafonova on January 2, 2024; (ii) a Form 4 filed on January 25, 2024 reporting 992 shares withheld to satisfy tax obligations in connection with vesting of restricted stock award units by Paul T. Lehr on January 2, 2024; (iii) a Form 4 filed on January 25, 2024 reporting 5,123 shares withheld to satisfy tax obligations in connection with vesting of restricted stock award units by Wa'el Hashad on January 2, 2024; (iv) a Form 4 filed on January 25, 2024 reporting 4,098 shares withheld to satisfy tax obligations in connection with vesting of restricted stock award units by Lisa A. Locklear on January 2, 2024; (v) a Form 4 filed on March 20, 2024 reporting the payment of 80,200 performance shares to Wa'el Hashad and a withholding of 32,866 shares for tax purposes on March 12, 2024; (vi) a Form 4 filed on June 7, 2024 reporting 325 shares withheld to satisfy tax obligations in connection with vesting of restricted stock award units by Paul T. Lehr on June 3, 2024; (vii) a Form 4 filed on August 7, 2024 reporting a grant of 16,000 restricted stock units to Neha Motwani, who was elected to the Board of Directors on July 2, 2024; and (viii) a Form 4 filed on August 7, 2024 reporting a grant of 16,000 restricted stock units to Roger Hajjar, who was elected to the Board of Directors on July 2, 2024.

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 2024 and 2023. Our NEOs for 2024 are as follows:

- Wa'el Hashad, Chief Executive Officer (CEO)
- Lisa Locklear, Chief Financial Officer (CFO), Treasurer
- Paul Lehr, General Counsel and Corporate Secretary

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 — 2024 and 2023* on page 93 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 other determined based on the Committee's discretion. Estimated bonus amounts earned in 2024 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 — 2024 and 2023* on page 93 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.

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 $23,000 for calendar year 2024, and other testing limits. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2024 may be up to an additional $7,500 above the statutory limit. 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.

Nonqualified Deferred Compensation. In 2024, we entered into a deferred compensation agreement with the CSO to defer payment of the consulting fees earned for services rendered as our Chief Science Officer during 2024 totalling $265,000. The 2024 consulting fees will be paid in the form of a lump sum distribution in February 2027. 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.

Summary Compensation Table — 2024 and 2023

Name and principal position	Year	Salary ($)	Stock awards ($)[1]	Option awards ($)[2]	Non-equity incentive plan compensation ($)[3]	All other compensation ($)[4]	Total ($)
Wa'el Hashad,	2024	570,973	765,675	70,725	389,550	51,816	1,848,739
Chief Executive Officer	2023	431,474	633,500	161,500	309,167	40,918	1,576,559
Lisa Locklear,	2024	430,923	429,885	39,975	189,000	33,468	1,123,251
Chief Financial Officer, Treasurer	2023	161,539	132,400	-	75,000	11,840	380,779
Paul Lehr,	2024	420,150	438,207	39,975	184,275	144,089	1,226,696
General Counsel and Corporate Secretary	2023	372,346	-	-	130,250	51,459	554,055

(1) The values set forth in this column are based on the aggregate grant date fair values of 2024 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.

(2) 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.

(3) Includes performance payouts at target for Company performance in 2024 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 2024, even though final performance payout will be calculated and approved by the Compensation Committee in March 2025.

(4) Other compensation represents 401(k) matching and health insurance costs paid by the Company. For Mr. Hashad, in 2024 this includes medical insurance of $34,566. For Mr. Lehr, in 2024 this includes medical insurance of $33,960 and a vacation accrual payout of $85,500 upon adoption of a new maximum vacation accrual limit policy.

Outstanding Equity Awards at Fiscal Year End Table - 2024

The following table sets forth information with respect to outstanding equity awards for each of our NEOs as of December 31, 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]	
Wa'el Hashad,	5,000	-	$ 36.20	3/1/2033 (2)	174,895	$ 302,568	(4)
Chief Executive Officer	2,396	26,354	$ 2.46	8/15/2034 (3)			
Lisa Locklear, Chief Financial Officer, Treasurer	1,355	14,895	$ 2.46	8/15/2034 (3)	120,520	$ 208,500	(4)
Paul Lehr,	4,688	312	$ 60.80	7/20/2031 (5)	44,687	$ 77,309	(4)
General Counsel and Corporate Secretary	500	-	$ 87.30	6/3/2032 (6)			
	1,573	712	$ 43.00	11/16/2032 (7)			
	1,355	14,895	$ 2.46	8/15/2034 (3)			

(1) Based on the value of $1.73 per share, the closing market price of our common stock on December 31, 2024.

(2) The option, granted March 1, 2023, fully vested on March 1, 2024. The number of shares and the exercise price were adjusted for the March 26, 2024 1:10 reverse stock split (the "Reverse Split").

(3) The option, granted on August 15, 2024, vests quarterly over 3 years beginning on October 1, 2024.

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

(5) The option, granted July 20, 2021, vested one-eighth on date of grant, with quarterly vesting over four years thereafter. The number of shares and the exercise price were adjusted for the March 26, 2024 Reverse Split.

(6) The option, granted June 3, 2022, was fully vested upon grant. The number of shares and the exercise price were adjusted for the March 26, 2024 1:10 reverse stock split.

(7) The option, granted November 16, 2022, vests 25% on March 1, 2023, then 6.25% each quarter thereafter. The number of shares and the exercise price were adjusted for the March 26, 2024 Reverse Split.

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.

The following table sets forth certain information regarding awards of options to our named executive officers during the fiscal year ended December 31, 2024 in the period beginning four business days before and ending one business day after the filing of a

periodic report on Form 10-Q or Form 10-K or the filing or furnishing of a Current Report on Form 8-K that discloses material nonpublic information and ending one business day after the filing or furnishing of such report:

Name (a)	Grant Date (b)	Number of securities underlying the award (c)	Exercise price of the award ($) (d)	Grant date fair value of the award (e)	Percentage change in the closing market price of the securities underlying the award between the trading day ending immediately prior to the disclosure of material nonpublic information and the trading day beginning immediately following the disclosure of material nonpublic information (f)
Wa'el Hashad Chief Executive Officer	8/15/2024	28,750	$2.46	$49,163	(5.75%)
Lisa A. Locklear, Chief Financial Officer, Treasurer	8/15/2024	16,250	$2.46	$27,788	(5.75%)
Paul Lehr General Counsel and Corporate Secretary	8/15/2024	16,250	$2.46	$27,788	(5.75%)

Employment Agreements/Letters with our NEOs

Mr. Wa'el Hashad. Pursuant to the terms of the letter agreement dated February 21, 2023, as amended January 17, 2025 ("Agreement") setting forth Mr. Hashad's compensation as Chief Executive Officer of the Company starting on March 1, 2023, Mr. Hashad receives an annual salary of $556,500 and will be eligible for an annual cash bonus of up to seventy percent (70%) 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 discretionary. Mr. Hashad received a signing bonus of 5,000 Restricted Stock Units, which vested in quarterly installments on each of April 1, 2023, July 1, 2023, September 1, 2023, and December 31, 2024. Mr. Hashad will also be eligible to receive annual long-term equity incentive awards through 2026 consisting of 5,000 shares of time-based vesting stock options and up to 12,500 of performance share units, in accordance with the terms of the Longeveron Second Amended and Restated 2021 Incentive Award Plan. 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 Form 10-K.

In the event of the Company's termination of Mr. Hashad's employment without Cause, as defined therein, he will be entitled to receive all unpaid but accrued bonuses for the prior year, three (3) months of base salary per each full year worked at the Company (with a minimum of 12 months of salary) payable in a lump sum, COBRA coverage for 18 months, and a bonus payment prorated based on date of termination. Mr. Hashad also entered into a Confidentiality and Nondisclosure Agreement simultaneously with this Agreement which imposed certain confidentiality, non-competition, non-disclosure obligations on Mr. Hashad.

Ms. Lisa Locklear. On July 14, 2023, the Company entered into a letter agreement ("Agreement") with Ms. Lisa 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 of 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. The Company has an employment agreement with Mr. Lehr, entered into on May 3, 2022 with an initial term of one year, with automatic one-year renewals thereafter, unless either party terminates the Agreement by providing 60 days written notice prior to the end of the then current term. The Company may terminate the Agreement for Cause (as defined therein), and Mr. Lehr may terminate the Agreement for a Good Reason (as defined therein). Under the terms of the Agreement, Mr. Lehr receives an annual salary of $409,500 and is eligible for an annual bonus based on the achievement of pre-established metrics agreed by Mr. Lehr and the CEO and/or the Compensation Committee. Mr. Lehr is also eligible to participate in the Company's Second Amended and Restated 2021 Incentive Award Plan.

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, severance equal to three months of base salary for each full year worked at the Company (not less than six months in any case), accelerated vesting of any unvested equity award, and 18 months of COBRA coverage, subject to execution and non-revocation of a standard release. The Agreement subjects Mr. Lehr to certain restrictive covenants which prohibit him from soliciting employees of the Company or working for businesses in competition with the Company for 24 months after the date of his employment termination with the Company. The Agreement also imposes certain confidentiality obligations on Mr. Lehr.

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.

Potential Payments Upon Termination or Change in Control

The terms of the Company's Second 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 - 2024. 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, 2024. Mr. Hashad, the Company's Chief Executive Officer, does not receive any additional compensation for 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[4]	$ 57,500	$ 39,771	$ —	$ 543,122	(5)	$ 640,393
Neil E. Hare[6]	$ 42,000	$ 57,810	$ —	$ —		$ 99,810
Rock Soffer	$ 43,750	$ 57,810	$ —	$ —		$ 101,560
Ursula Ungaro	$ 56,000	$ 57,810	$ —	$ —		$ 113,810
Khoso Baluch	$ 62,500	$ 57,810	$ —	$ —		$ 120,310
Richard Kender[7]	$ 36,946	$ 23,280	$ —	$ —		$ 60,226
Neha Motwani[8]	$ 29,250	$ 26,880	$ —	$ —		$ 56,130
Roger Hajjar, M.D.[8]	$ 29,375	$ 26,880	$ —	$ —		$ 56,255
Jeffrey Pfeffer[9]	$ 15,575	$ —	$ —	$ —		$ 15,575
Cathy Ross[10]	$ 18,283	$ —	$ —	$ —		$ 18,283
Douglas Losordo, M.D.[11]	$ 25,250	$ —	$ —	$ —		$ 25,250

(1) Amounts reflect fees paid relating to calendar 2024.

(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 to Dr. J. Hare, Mr. N. Hare, Mr. Soffer, Ms. Ungaro and Mr. Baluch on August 15, 2024. Additionally, Mr. Kender received an onboarding restricted stock award on May 9, 2024, while Ms. Motwani and Mr. Hajjar received their onboarding restricted stock awards on July 1, 2024. 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, 2024 was as follows:

	Unvested Stock Awards	Unvested Option Awards
Joshua M. Hare, M.D.	-	1,150
Neil E. Hare	7,333	1,150
Rock Soffer	7,333	1,150
Ursula Ungaro	7,333	1,150
Khoso Baluch	15,457	900
Richard Kender	13,334	-
Neha Motwani	14,667	-
Roger Hajjar, M.D.	14,667	-

(3) There were no stock options granted to directors in 2024.

(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 estimated value of complimentary Bahamas Registry Trial treatments ($14,000) received by the director and his guest, in addition to compensation received as the Chief Science Officer of the company, pursuant to his consulting agreement. In 2024, this compensation includes consulting fees of $265,000, estimated 2024 incentive compensation award of $119,250, and stock and option awards totaling $144,872 related to his consulting services. In 2024, we entered into a deferred compensation agreement with the CSO to defer payment of the consulting fees earned for services rendered as our Chief Science Officer during 2024 totaling $265,000. The 2024 consulting fees will be paid in the form of a lump sum distribution in February 2027.

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

(7) Mr. Kender was appointed to the Board of Directors to fill a vacancy on May 10, 2024.

(8) Ms. Motwani and Mr. Hajjar were elected to the Board of Directors on July 2, 2024.

(9) Mr. Pfeffer resigned from the Board on May 6, 2024.

(10) Ms. Ross resigned from the Board on May 8, 2024.

(11) Mr. Losordo did not stand for reelection to the Board so his term ended on July 2, 2024.

Summary of Director Compensation

The director compensation program provides for annual retainer fees and/or long-term equity awards for our directors. For the first half of 2024, each director received a prorated annual retainer of $35,000. A director serving as chairman of the Board or lead independent director received an additional prorated annual retainer of $15,000. Directors serving as the chairs of the audit, compensation and nominating and corporate governance, and finance committees received additional prorated annual retainers of $15,000, $10,000, $8,000, and $7,500, respectively. Directors serving as members of the audit, compensation, finance, and nominating and corporate governance committees received additional prorated annual retainers of $15,000, $10,000, $7,500 and $4,000, respectively. Beginning on July 1, 2024, each director received a prorated annual cash retainer of $45,000. A director serving as chairman of the Board received an additional prorated annual retainer of $20,000. Directors serving as the chairs of the Audit, Compensation, Nominating & Corporate Governance, and Science & Strategy (commencing in Q4 2024) committees

received additional prorated 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 (commencing in Q4 2024) committees received additional prorated 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 8,000 restricted stock units for each director, and initial grants upon joining the Board in 2024 are 16,000 restricted stock units of our Class A common stock, which shall be subject to vesting requirements.

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.

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 February 17, 2025 (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 13,473,898 shares of Class A common stock and 1,484,005 shares of Class B common stock as of February 17, 2025.

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:						
Donald M. Soffer	15,851	*	653,523	44.04%	21.95%	4.48%
Lee Cohen Hare	-	*	298,483	20.11%	0% [2]	2.00%
Named Executive Officers and Directors						
Joshua M. Hare, M.D. [3]	407,256	2.99%	462,808	31.19%	27.98%[2]	5.76%
Rock Soffer [4]	323,823	2.38%	41,010	2.76%	3.50%	2.42%
Ursula Ungaro [5]	18,551	*	-	*	*	*
Khoso Baluch [6]	12,593	*	-	*	*	*
Richard Kender [7]	5,333	*	-	*	*	*
Neha Motwani [7]	4,000	*	-	*	*	*
Roger Hajjar, M.D. [7]	4,000	*	-	*	*	*
Wa'el Hashad [8]	168,073	1.25%	-	*	1.12%	1.12%
Lisa Locklear [9]	65,528	*	-	*	*	*
Paul Lehr [10]	132,719	*	-	*	*	*
Nataliya Agafonova [9]	65,027	*	-	*	*	*
All Executive Officers and Directors as a Group (11 individuals)[9]:	**1,206,903**	**8.90%**	**503,818**	**33.95%**	**34.66%**	**11.35%**

* 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) 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. Dr. Hare's voting power percentage is inclusive of the amounts owned by Lee Cohen Hare.

(3) Amount includes 542 stock options and 148,936 warrants that are exercisable within 60 days of February 17, 2025. Amount also includes 533 shares held by an affiliated entity. Dr. Hare disclaims beneficial ownership except to the extent of his pecuniary interest.

(4) Amount includes 667 restricted stock units that may vest and 138,298 warrants that are exercisable within 60 days of February 17, 2025.

(5) Amount includes 667 restricted stock units that may vest within 60 days of February 17, 2025.

(6) Amount includes 2,000 restricted stock units that may vest within 60 days of February 17, 2025.

(7) Amount includes 1,333 restricted stock units that may vest within 60 days of February 17, 2025.

(8) Amount includes 26,354 restricted stock units that may vest and 2,396 stock options and 10,638 warrants that are exercisable within 60 days of February 17, 2025.

(9) Amount includes 14,895 restricted stock units that may vest and 1,354 stock options that are exercisable within 60 days of February 17, 2025.

(10) Amount includes 4,062 restricted stock units that may vest and 1,497 stock options that are exercisable within 60 days of February 17, 2025.

Equity Compensation Plan Information

The following table summarizes information, as of December 31, 2024, 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]	927,487	$ 3.98	205,704	[2]
Equity compensation plans not approved by security holders	-	-	-	
Total	927,487	$ 3.98	205,704	

(1) Represents outstanding awards pursuant to the Company's Second 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 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 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, 2024 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, 2024:

CSO Consulting Agreements

We entered into a consulting services agreement with Dr. Hare in November 2014 (the "Agreement"). The Agreement has an initial term of ten (10) years, with automatic renewals thereafter for four (4) year terms unless either party determines not to renew, provides for an initial annual fee structure of $265,000 and eligibility to participate in any incentive compensation

programs that are established for the Company. Under the terms of the Agreement, if Dr. Hare's employment is terminated without Cause (as defined below), Dr. Hare is entitled to receive a lump sum payment equal to the sum of (i) annual fees through the date of termination to the extent not previously paid, (ii) annual fees from the date of termination through the end of the Term (as though no termination had occurred), and (iii) any accrued but unpaid expenses. In the event Dr. Hare resigns for Good Reason (as defined below), then, subject to executing a release of claims and complying with 12-month non-solicit and non-compete covenants, Dr. Hare would be entitled to receive a lump sum payment equal to the sum of (i) annual fees through the date of termination to the extent not previously paid, (ii) annual fees from the date of termination through the end of the Term (as though no termination had occurred), plus an additional three (3) years, which shall include an annual increase in said fees of ten percent per year for each of the additional three (3) years, and (iii) any accrued but unpaid expenses. If Dr. Hare terminates the Agreement without Good Reason, then he shall receive the sum of (i) annual fees through the date of termination to the extent not previously paid, and (ii) any accrued but unpaid expenses. For purposes of this paragraph, Term is defined in the Agreement as the period commencing on the effective date and continuing through the tenth (10^{th}) anniversary of the effective date. Upon Dr. Hare's death or disability during the Term of the Agreement, he is entitled to receive any accrued and unremunerated fees or expenses; provided, however, that the Board has the discretion to choose to continue to pay fees for any period of time following a determination of disability.

The initial term of the agreement ended on November 22, 2024, however, the Company continues to operate under the same terms until a new agreement is executed. In addition, we entered into a deferred compensation agreement with the CSO to defer payment of the consulting fees earned for services rendered during 2024. The 2024 consulting fees will be paid in the form of a lump sum distribution in February 2027.

The Agreement acknowledges that Dr. Hare is employed by the University of Miami ("UM"), and remains subject to UM's policies, and also acknowledges that he serves as a consultant to enumerated outside entities. The Agreement outlines 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.

On November 16, 2022, the Company accounted for but had not issued 48,140 RSUs with an aggregate value of $0.2 million as payment for accrued expenses under the Agreement with the CSO. These shares were issued on May 24, 2023. As of December 31, 2024 and 2023, the Company had accrued balances due to the CSO of approximately $0.3 million and $0.1 million, respectively, included in other long-term liabilities and accrued expenses, respectively, and less than $0.1 million and approximately $0.1 million, respectively, included in accrued expense and accounts payable in the accompanying balance sheets.

JMHMD License Agreement

We are a licensee under an exclusive license agreement with JMHMD Holdings, LLC, an affiliate of our CSO and director, for the use of CD271+ cellular therapy technology, a subpopulation of bone marrow-derived mesenchymal stem cells. We are required to pay a royalty of one percent of the annual net sales of the licensed product(s) used, leased, or sold by or for us by any sub-licensees. If we sublicense the technology, we are also required to pay an amount equal to 10% of the net sales of the sub-licensees. 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, expenses related to the furtherance of the CD271 technology is being capitalized and amortized as incurred over 20 years. There were no license fees due during the years ended December 31, 2024 and 2023 pertaining to this agreement.

Participation in Capital Markets Transactions

On April 8, 2024, the Company commenced a public offering of up to 639,872 shares of the Company's Class A common stock, along with Pre-Funded Warrants to purchase up to an aggregate 1,572,894 shares of Class A common stock. The shares and Pre-Funded Warrants were sold together with Common Warrants to purchase up to an aggregate of 2,212,766 shares of Class A common stock. The combined public offering price was $2.35 per share and related Common Warrant and $2.349 per Pre-Funded Warrant and related Common Warrant. The Common Warrants were immediately exercisable and expire on April 10, 2029. Dr. Hare, our Chairman and Chief Science Officer, Mr. Rock Soffer, a member of our Board, and Mr. Hashad, our Chief Executive Officer each participated in the transaction.

Specifically, Dr. Hare purchased approximately $350,000 of Class A common stock and accompanying Common Warrants in this transaction. Dr. Hare's Common Warrants are exercisable for up to 148,396 shares of our Class A common stock at an exercise price of $2.35, a value of approximately $348,730.60, if such warrant is exercised at the exercise price. Mr. Rock Soffer

purchased approximately $325,000 of Class A common stock and accompanying Common Warrants in this transaction. Mr. Rock Soffer's Common Warrants are exercisable for up to 138,298 shares of our Class A common stock at an exercise price of $2.35, a value of approximately $325,000.30, if such warrant is exercised at the exercise price. Mr. Hashad purchased approximately $25,000 of Class A common stock and accompanying Common Warrants in this transaction. Mr. Hashad's Common Warrants are exercisable for up to 10,638 shares of our Class A common stock at an exercise price of $2.35, a value of $24,999.30, if such warrant is exercised at the exercise price.

Indemnification Agreements

We have indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of 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. For further information, see "Description of Capital Stock—Limitations on Liability and Indemnification Matters."

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 occurred prior to the adoption of this policy.

Item 14. Principal Accountant Fees and Services

The following is a summary of the fees billed to Longeveron by Marcum, the Company's current independent auditors, for professional services rendered for the fiscal years ended December 31, 2024 and 2023:

Fee Category	Fiscal 2024 Fees	Fiscal 2023 Fees
Audit Fees	$ 451,327	$ 283,410
Tax Fees	-	24,098
All Other Fees	-	3,085

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.

Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy that requires advance approval of all audit services and permitted non-audit services to be provided by the independent auditor as required by the Exchange Act. The Audit Committee must approve the permitted service before the independent auditor is engaged to perform it. 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.

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 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
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	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 Purchaser Warrant, incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed December 3, 2021
4.5	Form of Representative Warrant, incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed December 3, 2021
4.6	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
4.7	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.
4.8	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.
4.9	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.
4.10	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.
4.11	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
4.12	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
4.13	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
4.14	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
4.15	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
4.16	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
4.17	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
4.18	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
4.19	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
4.20	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
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#	Employment Agreement, effective August 12, 2020 by and between Longeveron LLC and James Clavijo, incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.5.1#	Separation Agreement and General Release, effective June 9, 2023, by and between Longeveron Inc. and James Clavijo, incorporated by reference to Exhibit 10.5.1 to the Registrant's Annual Report on Form 10-K filed on February 27, 2024.
10.6*	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
10.7*	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
10.8	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
10.9	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
10.9.1	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
10.9.2	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	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
10.11	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
10.12	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
10.13#	Employment Agreement between Longeveron Inc. and K. Chris Min, M.D., Ph.D., incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed April 5, 2022.
10.13.1#	Separation Agreement and General Release, effective March 31, 2023 between Longeveron Inc. and K. Chris Min, M.D. and Ph.D., incorporated by reference to Exhibit 10.13.1 to the Registrant's Annual Report on Form 10-K filed on February 27, 2024
10.14#	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.
10.15#	Employment Agreement between Longeveron Inc. and Paul Lehr dated May 3, 2022, incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K filed on February 27, 2024
10.16#	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
10.17#	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

10.18**	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
10.19**	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
10.20**	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
10.21	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
10.22	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
10.23	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
10.24**	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
10.25#	Employment Agreement between Longeveron Inc. and Wa'el Hashad, dated February 21, 2023, as amended January 17, 2025, filed herewith.
19.1	Longeveron Inc. Statement of Policy on Insider Trading, filed herewith
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 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
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
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).

** Schedules 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

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LONGEVERON INC

February 28, 2025

By: **/s/** Mohamed Wa'el Ahmed Hashad
Mohamed Wa'el Ahmed Hashad
Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated and, on the dates, indicated.

Signature	Title	Date
/s/ Mohamed Wa'el Ahmed Hashad Mohamed Wa'el Ahmed Hashad	Chief Executive Officer (principal executive officer)	February 28, 2025
/s/ Lisa A. Locklear Lisa A. Locklear	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	February 28, 2025
/s/ Joshua M. Hare Joshua M. Hare	Director	February 28, 2025
/s/ Khoso Baluch Khoso Baluch	Director	February 28, 2025
/s/ Rock Soffer Rock Soffer	Director	February 28, 2025
/s/ Roger Hajjar Roger Hajjar	Director	February 28, 2025
/s/ Richard Kender Richard Kender	Director	February 28, 2025
/s/ Neha Motwani Neha Motwani	Director	February 28, 2025
/s/ Ursula Ungaro Ursula Ungaro	Director	February 28, 2025

LONGEVERON, INC
FINANCIAL STATEMENTS

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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 sheets of Longeveron Inc. (the "Company") as of December 31, 2024 and 2023, the related statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audits, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the **two** years in the period ended December 31, 2024, 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 12 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2022**.**

Hartford, CT
February 28, 2025

Longeveron Inc.
Balance Sheets
(In thousands, except share data)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 19,232	$ 4,949
Marketable equity securities	-	412
Prepaid expenses and other current assets	308	376
Accounts and grants receivable	84	111
Total current assets	19,624	5,848
Property and equipment, net	2,449	2,529
Intangible assets, net	2,401	2,287
Operating lease asset	882	1,221
Other assets	202	193
Total assets	$ 25,558	$ 12,078
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	99	638
Accrued expenses	1,820	2,152
Current portion of operating lease liability	623	593
Deferred revenue	40	506
Total current liabilities	2,582	3,889
Long-term liabilities:		
Long-term portion of operating lease liability	824	1,448
Other liabilities	265	-
Total long-term liabilities	1,089	1,448
Total liabilities	3,671	5,337
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, 2024 and December 31, 2023	-	-
Class A common stock, $0.001 par value per share, 84,295,000 shares authorized, 13,407,441 shares issued and outstanding at December 31, 2024; 1,025,183 issued and outstanding at December 31, 2023	13	1
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, 2024; 1,485,560 issued and outstanding at December 31, 2023	1	1
Additional paid-in capital	131,480	91,823
Stock subscription receivable	-	(100)
Accumulated deficit	(109,607)	(84,984)
Total stockholders' equity	21,887	6,741
Total liabilities and stockholders' equity	$ 25,558	$ 12,078

See accompanying Notes to the Financial Statements.

Longeveron Inc.
Statements of Operations
(In thousands, except per share data)

	Year Ended December 31,	
	2024	**2023**
Revenues		
Clinical trial revenue	$ 1,402	$ 668
Contract manufacturing lease revenue	503	-
Contract manufacturing revenue	487	-
Grant revenue	-	41
Total revenues	2,392	709
Cost of revenues	508	488
Gross profit	1,884	221
Operating expenses		
General and administrative	10,269	12,184
Research and development	8,137	9,066
Total operating expenses	18,406	21,250
Loss from operations	(16,522)	(21,029)
Other income and (expense)		
Lawsuit expense	-	(30)
Other refundable tax credits	-	23
Other income (expense), net	549	(377)
Total other income (expenses), net	549	(384)
Net loss	$ (15,973)	$ (21,413)
Deemed dividend - warrant inducement offers	(8,650)	(798)
Net loss attributable to common stockholders	$ (24,623)	$ (22,211)
Basic and diluted net loss per share	$ (2.62)	$ (10.22)
Basic and diluted weighted average common shares outstanding	9,411,164	2,173,490

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	Accumulated Other Comprehensive Loss	Total Shareholder's equity
	Number	Amount	Number	Amount					
Balance at January 1, 2023	612,732	$ 1	1,489,109	$ 1	$ (100)	$ 83,731	$ (62,773)	$ (357)	$ 20,503
Conversion of Class B common stock for Class A Common Stock	3,555	-	(3,555)	-	-	-	-	-	-
Class A common stock issued for RSUs vested	25,308	-	-	-	-	-	-	-	-
Class A common stock, held for taxes on RSUs vested	(5,223)	-	-	-	-	(174)	-	-	(174)
Class A common stock issued for stock rights offering, net of issuance cost of $325	10,850	-	-	-	-	-	-	-	-
Class A common stock issued in direct placements, net of issuance costs of $1,229	372,030		-	-	-	5,338	-	-	5,338
Equity-based compensation	-	-	-	-	-	2,032	-	-	2,032
Dividend attributable to down round feature of 2021 warrants	-	-	-	-	-	798	(798)	-	-
Class A common stock issued for prefunded warrants	5,924	-	-	-	-	98	-	-	98
Reverse stock split rounding adjustment	7	-	6	-	-	-	-	-	-
Unrealized loss attributable to change in market value of available-for-sale securities	-	-	-	-	-	-	-	357	357
Net loss	-	-	-	-	-	-	(21,413)	-	(21,413)
Balance at December 31, 2023	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

See accompanying Notes to the Financial Statements.

Longeveron Inc.
Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (15,973)	$ (21,413)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	958	946
Interest earned on marketable securities	60	220
Equity-based compensation	2,328	2,032
Non-cash write-off of intangible assets	-	290
Changes in operating assets and liabilities:		
Accounts and grants receivable	27	107
Prepaid expenses and other current assets	68	28
Other assets	(9)	51
Accounts payable	(540)	(1,113)
Deferred revenue	(466)	-
Non-operating lawsuit expense	-	(1,398)
Accrued expenses	(332)	1,502
Operating lease asset and liability	(254)	(254)
Other liabilities	265	-
Net cash used in operating activities	(13,868)	(19,002)
Cash flows from investing activities:		
Proceeds from the sale of marketable securities	352	8,880
Acquisition of property and equipment	(655)	(301)
Acquisition of intangible assets	(337)	(393)
Net cash (used in) provided by investing activities	(640)	8,186
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of issuance cost	12,866	5,338
Proceeds from warrants exercised, net of issuance cost	16,191	98
Proceeds from stock subscription receivable	100	-
Payments for taxes on RSUs vested and PSUs vested	(366)	(174)
Net cash provided by financing activities	28,791	5,262
Change in cash and cash equivalents	14,283	(5,554)
Cash and cash equivalents at beginning of period	4,949	10,503
Cash and cash equivalents at end of period	$ 19,232	$ 4,949
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Vesting of RSUs into Class A Common Stock	(1,109)	(777)
Deemed dividend - warrant inducement offers	8,650	798

See accompanying Notes to the Financial Statements.

Longeveron Inc.
Notes to Financial Statements
December 31, 2024 and 2023

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 cellular therapies for specific aging-related and life-threatening conditions. 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. 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 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 $16.0 million and $21.4 million for the years ended December 31, 2024 and 2023, respectively. In addition, as of December 31, 2024, the Company had an accumulated deficit of $109.6 million. The Company expects to continue to generate operating losses for the foreseeable future.

As of December 31, 2024, the Company had cash and cash equivalents of $19.2 million. The Company currently believes that its cash and cash equivalents as of December 31, 2024 will enable it to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2025 based on its current operating budget and cash flow forecast. However, as a result of its successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, the Company has started to ramp up Biologics License Application (BLA) enabling activities as the Company currently anticipates a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. The Company's operating expenses and capital expenditure requirements are expected to accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase the Company's current proposed spend and further increase its capital investments. The Company intends to seek additional financing/capital raises/non-dilutive funding options 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.

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").

Certain reclassifications have been made to prior period amounts to conform to the current period presentation. These reclassifications had no impact on previously reported net loss for the year ended December 31, 2023.

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 condensed 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.

Accounting Standard Updates

A variety of proposed or otherwise potential accounting standards are currently under consideration by standard-setting organizations and certain regulatory agencies. Because of the tentative and preliminary nature of such proposed standards, management has not yet determined the effect, if any, that the implementation of such proposed standards would have on the Company's financial statements.

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, "Improvements to Reportable Segment Disclosures". The amendments in this ASU are intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and by extending the disclosure requirements to entities with a single reportable segment. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. ASU 2023-07 is to be applied retrospectively to all prior periods presented in the financial statements. ASU 2023-07 is effective for the Company for the annual period of its fiscal year ending December 31, 2024. The Company adopted this standard as of December 31, 2024, and the adoption did not have a material impact on its financial statements. See Note 13, *Segment Information*, for disclosures related to the adoption of ASU 2023-07.

In December 2023, the FASB issued ASU No. 2023-09, “Improvements to Income Tax Disclosures”. The amendments in this ASU change disclosure requirements for various items, including effective tax rate reconciliations and cash taxes paid. This ASU is effective for public companies for the financial reporting periods beginning on January 1, 2025, with early adoption permitted. The Company has not adopted ASU 2023-09 for its financial reporting period ending December 31, 2024, and does not anticipate the adoption of this ASU will have a material impact on its financial statements.

In November 2024, the FASB issued ASU No. 2024-03, “Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses”. The amendments in this ASU require additional disclosure about the nature of expenses included in the expense captions presented on the face of the income statement, including research and development and other operating expenses. This ASU is effective for public companies for the financial reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The requirements will be applied prospectively, with the option for retrospective application, and early adoption is permitted. ASU 2024-03 will be effective for the Company for the annual period of its fiscal year ending December 31, 2027. The Company is currently evaluating the impact of adopting this ASU on its financial statements.

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.

Marketable Securities:

The Company has no marketable securities at December 31, 2024. Marketable securities at December 31, 2023 consisted of marketable fixed income securities, primarily corporate bonds, as well as U.S. Government and agency obligations which are categorized as available-for-sale securities and are thus marked to market and stated at fair value in accordance with Accounting Standards Codification (“ASC”) 820 *Fair Value Measurement*. These investments are considered Level 1 and Level 2 investments within the ASC 820 fair value hierarchy. The fair value of Level 1 investments, including cash equivalents, money funds and U.S. government securities, are substantially based on quoted market prices. The fair value of corporate bonds is determined using standard market valuation methodologies, including discounted cash flows, matrix pricing and / or other similar techniques. The inputs to these valuation techniques include but are not limited to market interest rates, credit rating of the issuer or counterparty, industry sector of the issuer, coupon rate, call provisions, maturity, estimated duration and assumptions regarding liquidity and estimated future cash flows. In addition to bond characteristics, the valuation methodologies incorporate market data, such as actual trades completed, bids and actual dealer quotes, where such information is available. Accordingly, the estimated fair values are based on available market information and judgments about financial instruments categorized within Level 1 and Level 2 of the fair value hierarchy. Interest and dividends are recorded when earned. Realized gains and losses on investments are determined by specific identification and are recognized as incurred in the statement of operations. Changes in net unrealized gains and losses are reported in other comprehensive loss and represent the change in the fair value of investment holdings during the reporting period. Changes in net unrealized gains and losses were $0 and $0.3 million for the years ended December 31, 2024 and 2023, respectively.

Accounts and Grants Receivable:

Accounts and grants receivable include amounts due from customers, granting institutions and others. The amounts as of December 31, 2024 and 2023 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, as of (in thousands):

	December 31,	
	2024	**2023**
Accounts receivables from customers	$ 25	$ 15
National Institutes of Health – Grant	59	96
Total	$ 84	$ 111

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.

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 recoverable amounts, 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 $0 and $0.3 million impairment of long-lived assets during the years ended December 31, 2024 and 2023, respectively.

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. For the years ended December 31, 2024 and 2023, the Company recognized $0 of funds that were previously classified as deferred revenue. Due to the MSCRF – TEDCO – grant ARDS program being discontinued, the $0.4 million recorded as deferred revenue was reversed when the funds were returned to MSCRF – TEDCO.

Revenue Recognition:

The Company recognizes revenue when performance obligations related to respective revenue streams are met. For grant revenue, the Company considers the performance obligation met when the grant related expenses are incurred or supplies and materials are received. The Company is paid in tranches pursuant to terms of the related grant agreements, and then applies payments based on regular expense reimbursement submissions to grantors. There are no remaining performance obligations or variable consideration once grant expense reporting to the grantor is complete. 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 2024, the Company derived 100% of its contract manufacturing revenue from a single customer, resulting in a significant concentration of revenue risk. Should this customer terminate their business relationship, the Company's contract manufacturing revenue could be materially adversely impacted.

Revenue by source (in thousands):

	Year Ended December 31,	
	2024	**2023**
Clinical trial revenue	$ 1,402	$ 668
Contract manufacturing lease revenue	503	-
Contract manufacturing revenue	487	-
National Institute of Health - grant	-	41
Total	$ 2,392	$ 709

The Company records cost of revenues based on expenses directly related to revenue. For Grants, the Company records allocated expenses for Research and development costs to a grant as a cost of revenues. 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, including contract research organizations and clinical investigators, 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.

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, 2024 and 2023 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, 2024 and 2023, 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, 2024			
	Level 1	Level 2	Level 3	Total
Money market funds[1]	$ 6,877	$ -	$ -	$ 6,877
Accrued income	25	-	-	25
Total money market funds	$ 6,902	$ -	$ -	$ 6,902

	Fair Value at December 31, 2023			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$ -	$ 412	$ -	$ 412
Money market funds[1]	3,948	-	-	3,948
Accrued income	16	-	-	16
Total marketable securities	$ 3,964	$ 412	$ -	$ 4,376

(1) Money market funds are included in cash and cash equivalents in the balance sheets.

As of December 31, 2024 and 2023, the Company reported accrued interest receivable related to marketable securities and 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 marketable securities.

As of December 31, 2024 and 2023, the Company recorded no unrealized losses attributable to changes in marketable securities.

As of December 31, 2024 and 2023, the amortized cost of these securities was $0 and $0.4 million, respectively.

4. Property and Equipment, Net

Major components of property and equipment are as follows (in thousands):

	Useful Lives	December 31, 2024	December 31, 2023
Leasehold improvements	10 years	$ 4,402	$ 4,328
Furniture/Lab equipment	7 years	3,063	2,483
Computer equipment	5 years	120	120
Software/Website	3 years	38	38
Total property and equipment		7,623	6,969
Less accumulated depreciation and amortization		5,174	4,440
Property and equipment, net		$ 2,449	$ 2,529

Depreciation and amortization expense amounted to approximately $0.7 million for the years ended December 31, 2024 and 2023.

5. Intangible Assets, Net

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		1,273	—	1,273
Trademark costs		217	—	217
Total		$ 3,533	$ (1,132)	$ 2,401

Major components of intangible assets as of December 31, 2023, are as follows (in thousands):

	Useful Lives	Cost	Accumulated Amortization	Total
License agreements	20 years	$ 2,043	$ (909)	$ 1,134
Patent costs		959	–	959
Trademark costs		194	–	194
Total		$ 3,196	$ (909)	$ 2,287

Amortization expense related to intangible assets amounted to approximately $0.2 million for the years ended December 31, 2024 and 2023. During the year ended December 31, 2024 and 2023, the Company wrote-off $0 million and $0.3 million, respectively, of abandoned patents that it was no longer pursuing in several jurisdictions.

Future amortization expense for intangible assets as of December 31, 2024 is approximately as follows (in thousands):

Year Ending December 31,	Amount
2025	$ 224
2026	102
2027	61
2028	61
2029	61
Thereafter	402
Total	$ 911

6. Leases

The Company records a right-of-use operating lease asset and a lease liability related to its operating leases (there are no finance leases). The Company's corporate office lease expires in March 2027. As of December 31, 2024, the operating lease asset and operating lease liability were approximately $0.9 million and $1.4 million, respectively. As of December 31, 2023, the operating lease asset and operating lease liability were approximately $1.2 million and $2.0 million, respectively.

Future minimum payments under the operating leases as of December 31, 2024 are as follows (in thousands):

Year Ending December 31,	Amount
2025	682
2026	682
2027	169
Total	1,533
Less interest (5% discount rate)	(86)
Present value of lease liability	$ 1,447

During the years ended December 31, 2024 and 2023, the Company incurred approximately $0.8 million and $0.9 million, respectively, of total lease costs that are included in the general and administrative expenses in the statements of operations.

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, 2024, stockholders exchanged 1,555 shares of Class B common stock for 1,555 shares of Class A common stock. During the year ended December 31, 2023, stockholders exchanged 3,555 shares of Class B common stock for 3,555 shares of Class A common stock.

Warrants

Summary of Warrant Issuances

As part of the Company's initial public offering ("IPO"), the underwriter received warrants to purchase up to 10,640 shares of Class A common stock. The warrants are exercisable at any time and from time to time, in whole or in part, during the four and a half-year period commencing August 12, 2021, at a price of $120.00 per share and the fair value of warrants was approximately $0.5 million. During 2021, the underwriters assigned 9,576 of the warrants to its employees.

As part of the Company's 2021 private placement offering, the Company issued warrants to investors to purchase up to an aggregate of 116,935 shares of Class A common stock, equal to the number of shares of Class A common stock purchased by such investor in the offering, at an exercise price of $175.00 per share , which were immediately exercisable, were set to expire five years from the date of issuance, and had certain downward pricing adjustment mechanisms, subject to a floor, as set forth in greater detail therein (the "Purchaser Warrants"). In addition, the Company granted the underwriters warrants, under similar terms, to purchase 4,679 shares of Class A common stock, at an exercise price of $175.00 per share. On August 16, 2023, the Company announced its Stock Rights Offering, which triggered the downward pricing mechanism on the Purchaser Warrants, at which time these warrants were adjusted downward to an exercise price of $52.50 for the period remaining through expiration. This resulted in a deemed dividend to common stockholders of approximately $0.8 million for the change in the fair value of the warrants using a Black-Scholes pricing model.

On December 15, 2021, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-261667) registering the resale of an aggregate of 238,535 shares of Class A common stock, including (i) 116,935 shares issued to purchasers in the Company's 2021 private placement offering; (ii) up to 116,935 shares issuable upon exercise of the Purchaser Warrants; and (iii)

4,679 shares issuable upon exercise of the underwriters warrants issued as part of the 2021 private placement offering. The Form S-1 was declared effective by the SEC on December 22, 2021.

As part of an October 2023 registered direct offering, the Company issued Series A warrants and Series B warrants to purchase up to 242,425 and 242,425, respectively, shares of Class A common stock. Each series of warrants had an exercise price of $16.50 per share, with the Series A warrants having a term of five and one-half (5.5) years from the date of issuance, and the Series B warrants having a term of eighteen (18) months from the date of issuance. Both the Series A and Series B warrants became exercisable as of December 26, 2023, following stockholder approval. In addition, the Company granted the placement agent warrants, under similar terms, to purchase 16,971 shares of Class A common stock, at an exercise price of $20.625 per share.

On November 15, 2023, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-275578) registering the resale of an aggregate of 501,821 shares of Class A common stock, including (i) up to 242,425 shares of issuable upon exercise of the Series A Warrants; (ii) up to 242,425 shares issuable upon exercise of the Series B Warrants; and (iii) 16,971 shares issuable upon exercise of warrants granted to the placement agent as part of the October 2023 registered direct offering. The Form S-1 was declared effective by the SEC on November 21, 2023.

In April 2024, the Series A Warrants and Series B Warrants were amended to reduce the exercise price to $2.35 per share. The Series A Warrants and Series B Warrants were subsequently exercised in full in April 2024.

As part of a December 2023 registered direct offering, the Company issued warrants to purchase an aggregate of 135,531 shares of Class A common stock. These warrants have an exercise price of $16.20 per share, became immediately issuable upon issuance, and expire on June 22, 2029. In addition, the Company granted the placement agent warrants, under similar terms, to purchase 9,489 shares of Class A common stock, at an exercise price of $21.813 per share.

On January 29, 2024, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-276745) registering the resale of an aggregate of 145,020 shares of Class A common stock, including (i) up to 135,531 shares issuable upon the exercise of warrants issued in a concurrent private placement in connection with the December 2023 registered direct offering and (ii) up to 9,489 shares issuable upon the exercise of warrants granted to the placement agent in connection with the December 2023 registered direct offering. The Form S-1 was subsequently amended by the Company on April 16, 2024 and declared effective by the SEC on April 17, 2024.

On April 8, 2024, the Company commenced a public offering of up to 639,872 shares of the Company's Class A common stock, along with pre-funded warrants to purchase up to an aggregate 1,572,894 shares of Class A common stock (the "Pre-Funded Warrants"). The shares and Pre-Funded Warrants were sold together with warrants to purchase up to an aggregate of 2,212,766 shares of Common Stock (the "Common Warrants"). The combined public offering price was $2.35 per share and related Common Warrant and $2.349 per Pre-Funded Warrant and related Common Warrant. Subject to certain limitations, the Pre-Funded Warrants were immediately exercisable and could be exercised at a nominal consideration of $0.001 per share of Class A common stock at any time until all of the Pre-Funded Warrants were exercised in full. The Common Warrants were immediately exercisable and expire on April 10, 2029.

As compensation to the placement agent the Company also issued to designees of the placement agent warrants to purchase up to 154,894 shares of Class A common stock, which had substantially the same terms as the Common Warrants, and with an exercise price of $2.9375 per share and a term of five years from the commencement of sales in the offering.

In connection with the offering, the Company also entered into an agreement with a holder of existing warrants to amend the holder's existing Series A warrants and Series B warrants to reduce the exercise price to $2.35 per share and (ii) amend the expiration date of the Series A Warrants to five and one-half (5.5) years following the closing of the public offering and the Series B warrants to eighteen (18) months following the closing of the public offering, in each case for a payment to the Company of $0.125 per amended warrant.

On April 16, 2024, the Company entered into inducement letter agreements with certain holders of its existing Series A warrants and Series B warrants, and Common Warrants issued on April 10, 2024, whereby the holders agreed to exercise the warrants for cash at the exercise price of $2.35 per share in consideration for payment of $0.125 per new warrant and for the Company's agreement to issue new unregistered Class A common stock warrants to purchase up to 4,799,488 shares of Class A common stock at an exercise price of $2.35 per share, and which were immediately exercisable upon issuance. The warrants to purchase up to 2,399,744 shares of Class A common stock (the "Series C Warrants") have a term of five (5) years from the issuance date, and the warrants to purchase up to 2,399,744 shares of Class A common stock (the "Series D Warrants") have a term of twenty-four (24) months from the issuance date, with all of the Series C Warrants and Series D Warrants being immediately exercisable. All

of the Series D Warrants were exercised in June 2024, pursuant to ordinary course exercise as well as a subsequent inducement transaction.

Additionally, the Company issued to the placement agent or its designees as compensation, warrants to purchase up to 167,982 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued upon exercise of the warrants pursuant to the inducement transaction, which had the same terms as the Series C Warrants, except that the placement agent warrants have an exercise price of $3.25 per share.

Furthermore, upon exercise, if any, of the Series D Warrants for cash, the Company agreed to issue the placement agent or its designees, within five (5) business days of the Company's receipt of the exercise price, warrants to purchase the number of shares of Class A common stock equal to 7.0% of the aggregate number of shares underlying such Series D Warrants that have been exercised, with such warrants to be in the same form and terms as the prior placement agent warrants.

On April 18, 2024, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-278995) registering the resale of an aggregate of 4,967,470 shares of Class A common stock issuable upon exercise of certain warrants, including (i) up to 2,399,744 shares issuable upon the exercise of the Series C Warrants issued in the April 2024 warrant inducement transaction; (ii) up to 2,399,744 shares issuable upon the exercise of the Series D Warrants issued in the April 2024 warrant inducement transaction; and (iii) up to 167,982 shares issuable upon exercise of the warrants issued to the placement agent or its designees in the April 2024 warrant inducement transaction. The Form S-1 was subsequently amended by the Company and declared effective by the SEC on May 21, 2024.

On June 17, 2024, the Company entered into additional inducement letter agreements with the holders of its existing Series D Warrants to exercise the remaining 1,697,891 shares of Class A common stock underlying Series D Warrants that remained outstanding for cash at the exercise price of $2.35 per share in consideration for the Company's agreement to issue new unregistered Class A common stock warrants (the "June Inducement Warrants"), for payment of $0.125 per new warrant, to purchase up to an aggregate of 3,395,782 shares of Class A common stock at an exercise price of $2.50 per share and which were immediately exercisable upon issuance and have a term of twenty-four (24) months from the issuance date.

The Company also issued to the placement agent or its designees as compensation, (i) warrants to purchase up to 118,852 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued upon exercise of the warrants pursuant to the June inducement transaction and (ii) warrants to purchase up to an aggregate of 49,130 shares of Common Stock, equal to 7.0% of the aggregate number of shares of Common Stock issued upon exercise of certain Series D warrants prior to the inducement transaction, which had substantially the same terms as the June Inducement Warrants, except that the warrants exercisable for 118,852 shares had an exercise price of $3.25 per share and the warrants exercisable for 49,130 shares had an exercise price of $2.9375 per share, respectively (collectively, the "June placement agent warrants").

Upon exercise, if any, of the June Inducement Warrants for cash, the Company agreed to issue within five (5) business days to the placement agent or its designees, warrants to purchase the number of shares of Class A common stock equal to 7.0% of the aggregate number of shares of Class A common stock underlying such June Inducement Warrants that have been exercised, with such warrants to be in the same form and terms as the June placement agent warrants.

The issuance under the inducement offers represented $8.5 million in additional value provided to the investors, which was recorded as a deemed dividend to common stockholders. The June Inducement Warrants expire on June 18, 2026.

On June 28, 2024, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-280577) registering the resale of an aggregate of 3,563,764 shares of Class A common stock issuable upon exercise of certain warrants, including (i) up to 3,395,782 shares issuable upon the exercise of the June Inducement Warrants and (ii) up to 167,982 shares issuable upon the exercise of the June placement agent warrants. The Form S-1 was subsequently declared effective by the SEC on July 9, 2024.

On July 10, 2024, a holder exercised Series C warrants for 50,000 shares of Class A common stock for cash (the "July Series C warrant exercise").

On July 10, 2024, certain holders of warrants issued in June of 2024 exercised warrants to purchase an aggregate of 150,000 shares of Class A common stock for cash (the "July 10 warrant exercise"). In addition, on July 17, 2024, the Company issued to the placement agent warrants to purchase up to 10,500 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued in the July 10 warrant exercise (the "first tranche July ordinary course placement agent warrants"). The first tranche July ordinary course placement agent warrants have substantially the same terms as the June placement agent warrants, except that the first tranche July ordinary course placement agent warrants (i) have an exercise price of $3.125 per share and (ii) expire July 17, 2026.

On July 17, 2024, a holder of the June Inducement Warrants exercised the same to purchase 2,319,186 shares of Class A common stock for cash (the "July 17 warrant exercise" and together with the July 10 warrant exercise and the July Series C warrant exercise, collectively, the "July warrant exercises"). Accordingly, on July 24, 2024, the Company issued to the placement agent warrants to purchase up to 162,344 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued in the July 17 warrant exercise (the "second tranche July ordinary course placement agent warrants", and together with the first tranche July ordinary course placement agent warrants, the "July ordinary course placement agent warrants", and collectively with the July offering placement agent warrants, the "July placement agent warrants"). The second tranche July ordinary course placement agent warrants have substantially the same terms as the first tranche July ordinary course placement agent warrants, except that the second tranche July ordinary course placement agent warrants expire July 24, 2026.

The gross proceeds to the Company from the July warrant exercises, inclusive of the payment consideration for such Series C warrants and June Inducement Warrants, were approximately $6.3 million, inclusive of the payment consideration for such warrants, before deducting placement agent fees payable by the Company.

On July 18, 2024, the Company entered into a securities purchase agreement with institutional and accredited investors relating to the registered direct offering and sale of an aggregate of 2,236,026 shares of our Class A common stock at a purchase price of $4.025 per share of Class A common stock and associated warrant (the "July registered direct offering"). The securities issued in the July registered direct offering were offered pursuant to a prospectus supplement, dated July 18, 2024, and accompanying prospectus, in connection with a takedown from our shelf registration statement on Form S-3 (File No. 333-264142), which was declared effective by the SEC on April 14, 2022.

In a concurrent private placement (the "July private placement" and together with the July registered direct offering, the "July offering"), the Company also sold unregistered Class A common stock warrants to purchase up to an aggregate of 2,236,026 shares of our Class A common stock (the "July private placement warrants"). The unregistered July private placement warrants have an exercise price of $3.90 per share, became exercisable on July 19, 2024, and expire on July 20, 2026. In addition, the Company granted the placement agent warrants, under similar terms, to purchase 156,522 shares of Class A common stock, at an exercise price of $5.0313 (the "July offering placement agent warrants"). The gross proceeds to the Company from the July offering were approximately $9.0 million, before deducting placement agent fees and other offering expenses payable by the Company.

On August 6, 2024, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-281299) registering the resale of an aggregate of 2,565,392 shares of Class A common stock issuable upon exercise of certain warrants, of which (i) up to 2,236,026 shares are issuable upon the exercise of the July private placement warrants issued to the purchasers upon the closing of the July private placement; (ii) 156,522 shares are issuable upon exercise of the July offering placement agent warrants issued to Wainwright, or its designees, pursuant to the terms of the current engagement Letter with Wainwright; and (iii) 172,844 shares are issuable upon exercise of the July ordinary course placement agent warrants issued to Wainwright, or its designees, pursuant to the terms of a then-applicable engagement letter with Wainwright, in connection with previously exercised June Inducement Warrants. The Form S-1 was declared effective by the SEC on August 12, 2024.

In September 2024, the Company entered into additional inducement letter agreements with certain holders of its existing Purchaser Warrants issued as part of the Company's 2021 private placement offering to amend and reduce the exercise price of the Purchaser Warrants to $1.00 per share in consideration for the holders' cash exercise of all Purchaser Warrants held by such holder on or before September 27, 2024. In connection with the September 2024 inducement transaction, Purchaser Warrants were exercised for 114,077 shares of Class A common stock, resulting in gross proceeds to the Company of $114,077.

In October 2024, the Company entered into additional inducement letter agreements with the remaining holders of its existing Purchaser Warrants issued as part of the Company's 2021 private placement offering to amend and reduce the exercise price of the Purchaser Warrants to $1.00 per share in consideration for the holders' cash exercise of all Purchaser Warrants held by such holder. In connection with the October 2024 inducement transaction, Purchaser Warrants were exercised for 2,858 shares of Class A common stock, resulting in gross proceeds to the Company of $2,858. The Purchaser Warrants have been exercised in full.

Summary of Warrants Outstanding

As of December 31, 2024, warrants exercisable for an aggregate of up to 6,802,668 shares of the Company's Class A common stock remain outstanding. This includes:

- IPO underwriter warrants exercisable for up to 5,536 shares of Class A common stock at an exercise price of $120.00 per share, which expire February 12, 2026.
- Underwriter warrants issued in connection with the 2021 private placement offering 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.
- Placement agent warrants issued in connection with the October 2023 registered direct offering 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.
- Investor warrants issued in connection with the December 2023 registered direct offering 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.
- Placement agent warrants issued in connection with the December 2023 registered direct offering 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.
- Common Warrants issued in connection with the April 2024 public offering 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.
- Placement agent warrants issued in connection with the April 2024 public offering 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.
- Series C Warrants issued in connection with the April 2024 inducement transaction 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.
- Placement agent warrants issued in connection with the April 2024 inducement transaction 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.
- June placement agent warrants issued in the ordinary course prior to the June 2024 inducement transaction 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.
- June Inducement 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.
- Placement agent warrants issued in connection with the June 2024 inducement transaction 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.
- First tranche July ordinary course placement agent 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.
- Second tranche July ordinary course placement agent 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.
- July private placement 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.
- July offering placement agent 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.

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 twice (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, 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.

During the year ended December 31, 2023, a total of 25,308 RSUs vested for Class A common stock shares. Of that amount, the Company withheld 5,223 Class A common stock shares to satisfy employee tax liabilities. The shares withheld are available for reissuance pursuant to the Company's Second Amended and Restated 2021 Incentive Award Plan. Each RSU grant made during 2024 and 2023 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, 2024 and 2023, the Company had 806,001 and 11,239, respectively RSUs outstanding (unvested).

RSU activity for the year ended December 31, 2024 was as follows:

	Number of RSUs
Outstanding (unvested) at December 31, 2023	11,239
RSUs granted	1,394,774
RSUs vested	(566,904)
RSU expired/forfeited	(33,108)
Outstanding (unvested) at December 31, 2024	806,001

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.

In 2024, the Company granted options that vest quarterly over three years. Non-employee awards, including options granted to directors and certain third-party service providers, are granted similar to the Company's employee awards.

In 2023, the Company granted options to executives and non-employee directors under various vesting schedules, including a four-year vesting period with 25% vesting per year and a one-year cliff vesting for the CEO.

The fair value of the options issued are estimated using the Black-Scholes option-pricing model. For 2024, the following assumptions were used: 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 of 3.79% - 4.52%. For 2023, the following assumptions were used: a dividend yield of 0%; an expected life of 10 years; volatility ranging from 90%-95%; and risk-free interest rate based on the grant date ranging from of 3.89% to 4.01%. Each option grant made during 2024 and 2023, will be expensed ratably over the option vesting periods, with prorated adjustments made as needed to align with grant dates and applicable service periods.

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. Also, as of December 31, 2023, the Company has recorded issued and outstanding options to purchase a total of 43,786 shares of Class A common stock pursuant to the 2021 Incentive Plan, at a weighted average exercise price of $4.96 per share.

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

For the year ended December 31, 2023:

	Number of Stock Options
Stock options vested (based on ratable vesting)	16,091
Stock options unvested	27,695
Total stock options outstanding at December 31, 2023	43,786

Stock Option activity for the year ended December 31, 2024 was as follows:

	Number of Stock Options	Weighted Average Exercise Price
Outstanding at December 31, 2023	43,786	$ 49.60
Options granted	88,625	2.46
Options exercised	-	-
Options expired/forfeited	(11,225)	50.20
Outstanding at December 31, 2024	121,186	$ 15.09

For the years ended December 31, 2024 and 2023, the equity-based compensation expense amounted to approximately $2.3 million and $2.0 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, 2024 and 2023.

As of December 31, 2024, the remaining unrecognized RSUs compensation of approximately $1.6 million will be recognized over approximately 2.08 years. The remaining unrecognized stock options compensation of approximately $0.3 million will be recognized over approximately 1.94 years.

9. Commitments and Contingencies

Master Services and Clinical Studies Agreements:

As of December 31, 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. 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 the agreement, the Company has agreed to pay the CSO $265,000 annually. The compensation payments are for scientific knowledge, medical research, technical knowledge, skills, and abilities to be provided by the CSO to further develop the intellectual property rights assigned by the CSO to the Company. This agreement requires the CSO to also assign to the Company the exclusive right, title, and interest in any work product developed from his efforts during the term of this agreement. On November 16, 2022, the Company accounted for but had not issued 48,140 RSUs convertible to unregistered shares of Class A common stock, with an aggregate value of $207,000 as payment for accrued expenses under a consulting agreement with the CSO. These shares were issued on May 24, 2023. The initial term of the agreement ended on November 22, 2024, however, the Company continues to operate under the same terms until a new agreement is executed. 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. The 2024 consulting fees will be paid in the form of a lump sum distribution in February 2027. As of December 31, 2024 and 2023, the Company had accrued balances due to the CSO of approximately $0.3 million and $0.1 million, respectively, included in other long-term liabilities and accrued expenses, respectively, and less than $0.1 million and approximately $0.1 million, respectively, included in accrued expense and accounts payable in the accompanying balance sheets.

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 of $242,400 upon signing of the Secretome Agreement, which was comprised of (a) technology transfer, documentation preparation, training, and testing costs of $210,000, (b) a ten-hour prepayment of project management fees of $2,400, and (c) a first month suite reservation fee of $30,000. The Company will bill Secretome on a variable fee basis for quality control, in process, release, and stability testing service items. For each Product lot, Secretome will pay the Company $55,000 per lot as well as a $30,000 for each additional

Product lot in excess of two initial "training run" lots. Secretome will also pay a $30,000 monthly manufacturing suite reservation fee to the Company as well as a $240 per hour hourly fee for project management services.

Secretome has also agreed to compensate the Company for the value of all materials involved in manufacturing and quality control testing the Product, plus a 20 percent markup on these materials. For any outsourced testing, Secretome will be billed directly by the laboratory conducting the testing, plus a fee of $500 per batch payable to the Company. Furthermore, Secretome will pay the Company $2,000 monthly for storage of in process samples, vialed harvests for training, and in process samples for Product lots. The Company will receive certain variable payments related to product packing, handling and shipping, with a standard fee of $750, with an increased fee of $1,500 for expedited or special hour service.

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. In addition, either party may terminate the agreement immediately in the event the other party seeks the protection of any bankruptcy court, becomes insolvent, makes an assignment for the benefit of creditors, or any debarment activity occurs with respect to that party. A force majeure provision also permits termination of the Secretome Agreement upon written notice to the other party as a result of a delay or interference of performance continuing for more than 60 days.

For the year ended December 31, 2024, the Company has earned revenues of $1.0 million under the Secretome Agreement.

The Company is also a party to a Mutual Nondisclosure Agreement with Secretome, signed and effective as of October 24, 2023 (the "Nondisclosure Agreement"), by which both parties have agreed to maintain the strict confidentiality of, restrict access to, and not to disclose any intellectual property, trade secrets, business dealings, customers, operations, products, research, clinical data, or other competitively sensitive or proprietary confidential information shared between them, subject to certain customary carve-outs for disclosures pursuant to applicable law or filings with regulatory or governmental agencies including the SEC. The Nondisclosure Agreement has a term of ten years from the later of (i) the effective date of the Nondisclosure Agreement, (ii) the date of the last disclosure of information under the Secretome Agreement, any "Quality Agreement" which may be entered into between the parties, or any scope of work; or (iii) the expiration of any patents issued arising out of or resulting from the confidential information. The Nondisclosure Agreement will not terminate with respect to trade secrets.

Exclusive Licensing Agreements:

UM Agreement

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 mesenchymal stem cells 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 fifty thousand dollars, 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 110,387 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"), biologics application ("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. Food and Drug Administration, 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 Hypoplastic Left Heart Syndrome ("HLHS")

investigational new drug application ("IND") with ckit+ cells; and (b) UMP-438 titled "Method of Determining Responsiveness to Cell Therapy in Dilated Cardiomyopathy."

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 $200,000 to UM, and as of December 31, 2024 and 2023, in the accompanying balance sheets, the Company had accrued $50,000 in milestone fees payable to UM for both years, and $15,000 for both years, respectively, for patent related reimbursements based on the estimated progress to date.

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" and having inventors Joshua Hare and Konstantinos Chatzistergos. 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 certain 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: (c) $150,000 upon completion of the first Phase 3 Clinical Trial; and (d) $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, 2024, 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. The Company recorded the value of the cash consideration and membership units issued to obtain this license agreement as an intangible asset. The Company is required to pay as royalty 1% of the annual net sales of the licensed product(s) used, leased, or sold by or for licensee or its sub-licensees. 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. In addition, on December 23, 2016, as required by the license agreement, the Company paid an initial fee of $250,000 to JMHMD, and issued to it 10,000 Series C Units, valued at $250,000. The $0.5 million of value provided to JMHMD for the license agreement, along with professional fees of approximately $27,000, were recorded as an intangible asset that is amortized over the life of the license agreement which was defined as 20 years. Further, expenses related to the furtherance of the CD271+ technology is being capitalized and amortized as incurred over 20 years. There were no license fees due for the years ended December 31, 2024 and 2023 pertaining to this agreement.

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, 2024, the Company is not aware of any legal proceedings or material developments requiring disclosure.

On September 13, 2021, the Company and certain of its directors and officers were named as defendants in a securities lawsuit filed in the U.S. District Court for the Southern District of Florida and brought on behalf of a purported class. The suit alleges there were materially false and misleading statements made (or omissions of required information) in the Company's initial

public offering materials and in other disclosures during the period from our initial public offering on February 12, 2021, through August 12, 2021, in violation of the federal securities laws. The action sought damages on behalf of a proposed class of purchasers of the Company's common stock during said period. On July 12, 2022, all parties preliminarily agreed to settle the action for approximately $1.4 million, which settlement was preliminarily approved by the Court on or about May 12, 2023, and which settlement amount was paid on May 24, 2023. Legal expenses incurred in ordinary business activities are reported within general and administrative expenses.

On or about May 18, 2023, a former employee of the Company filed a charge with the Equal Employment Opportunities Commission ("EEOC") and the Florida Commission on Human Relations alleging discrimination based on disability, and on or about August 15, 2023, the former employee filed a complaint in Miami-Dade Circuit Court alleging unpaid wages were outstanding. Both matters were addressed and fully resolved and settled in a mediation between the Company and the former employee held on September 28, 2023, by which it was agreed that the former employee would be paid $75,000 (a total of $35,000 towards this resolution was paid by the Company and all remaining costs were covered by the Company's insurance carrier) and that the EEOC and FCHR charges were withdrawn and the action in the Miami-Dade Circuit Court was dismissed with prejudice.

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 $154,000 and $131,000 to the Plan during the years ended December 31, 2024 and 2023, 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, 2024 and December 31, 2023 (in thousands):

	2024	2023
Deferred tax assets:		
Net operating loss carry forwards	$ 10,870	$ 7,790
ASC 842 Lease liability	361	514
Equity based compensation	244	201
Fixed assets	-	-
Intangible assets	158	106
Capitalized research & development expenses	4,283	3,830
Tax credits	1,866	1,258
Accrual to cash adjustment	-	-
Other	466	468
Total deferred tax assets	18,248	14,167
Valuation allowance	(18,014)	(13,776)
Deferred tax assets, net of valuation allowance	234	391
Deferred tax liabilities:		
ASC 842 Right-of-use asset	(220)	(307)
Depreciation and amortization	(14)	(84)
Total deferred tax liabilities	(234)	(391)
Deferred tax assets and liabilities, net of valuation allowance	$ -	$ -

As of December 31, 2024, the Company had NOL carryforwards for federal purposes of approximately $43.4 million, all of which have no expiration. The Company also had state NOL carryforwards of approximately $40.4 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 50% 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.

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2024 and 2023 were as follows:

	2024	2023
Federal tax at statutory rate	21.0%	21.0%
State tax benefits, net of federal benefit	3.9	4.2
Other	1.6	1.6
Change in valuation allowance	(26.5)	(26.7)
Income tax benefit	-%	-%

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, 2024, 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, 2024 and 2023.

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,	
	2024	2023
RSUs	806	112
PSUs	-	125
Stock options	121	438
Warrants	6,803	7,740
Total	7,730	8,415

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, 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, 2024 and 2023.

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,	
	2024	2023
Revenues[1]	$ 2,392	$ 709
Less:		
Cost of revenues	508	488
R&D costs[2]	2,799	5,704
G&A costs[3]	5,646	6,869
Personnel costs[4]	9,002	7,731
Other segment items[5]	410	1,330
Net loss	$ (15,973)	$ (21,413)

(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

EXHIBIT 10.25

February 21, 2023, as amended January 17, 2025

Dear Wa'el:

This letter agreement (this "Agreement") sets forth the terms and conditions of your employment with Longeveron Inc. (the "Company"), which shall be effective as of March 1, 2023 (the "Effective Date"). This Agreement will govern your employment with the Company following the Effective Date on the following terms and conditions:

1. **Term**. The term of your employment with the Company will terminate upon delivery to you by the Company of notice to such effect, which notice may be given for any or no reason, or upon your earlier resignation, death or Disability. You acknowledge that no provision contained in this Agreement will entitle you to remain in the employment of the Company for any specific period of time or affect the right of the Company to terminate your employment hereunder at any time for any reason, subject to compliance with the termination provisions set forth herein. The period during which you are employed by the Company pursuant to this Agreement shall be referred to as the "Term." For purposes of this Agreement, "Disability" shall mean your inability, due to physical or mental incapacity, to perform the essential functions of the your job, for one hundred eighty (180) days out of any three hundred sixty-five (365) day period or one hundred twenty (120) consecutive days or receiving any disability benefits under a Company plan for a period of one hundred twenty (120) consecutive days or longer.

2. **Position, Duties and Reporting**. Your position will be Chief Executive Officer of the Company and you will join the Company Board of Directors when such position is available without violating any requirements under Nasdaq, and without any additional payment for such position. You will report directly to the Board of Directors (the "Board") of the Company. You shall be employed by the Company on a full-time basis and shall perform such duties and responsibilities on behalf of the Company as are consistent with your position, as may be designated from time to time by the Board. You will be required to devote all of your business time to the business and affairs of the Company and to the promotion of its interests. Notwithstanding the foregoing, you may engage in other activities such as personal investments or business ventures that do not involve a conflict of interest or civic and charitable activities, so long as: (i) such activities do not interfere or conflict with your duties and obligations hereunder and (ii) such activities are disclosed in advance to the Board. In addition, you shall be permitted to serve as a director on up to two (2) other company's Board of Directors so long as they do not compete with Company and subject to the prior consent of the Board (which will not be unreasonably withheld).

3. Compensation and Benefits.

a. Base Salary. During the Term, your annual base salary will be Five Hundred and Thirty Thousand Dollars ($530,000.00) per year and will be payable in accordance with the Company's normal payroll practices, less the applicable taxes and elective withholdings. Your base salary may be subject to review and adjustment on an annual basis, as determined by the Board or the Compensation Committee of the Board (the "Compensation Committee").

b. Incentive Bonus Eligibility. During the Term, you will be eligible for an annual cash bonus pursuant to the Company's annual cash bonus program. Your initial aggregate target bonus will be in an amount up to 70% of your base salary ("Target Bonus"). With respect to the Target Bonus, eighty percent (80%) of the Target Bonus amount will be based on the achievement of performance criteria established by the Compensation Committee for the applicable fiscal year, which may include both corporate goals and individual criteria; twenty percent (20~~30~~%) of the Target Bonus amount will be at the discretion of the Board or the Compensation Committee. The actual amount of any bonus earned shall be determined in the discretion of and by the Compensation Committee or the Board based on achievement of the applicable performance criteria and the program terms and discretionary considerations after the end of the applicable fiscal year. Except as otherwise provided herein, you will be entitled to receive any earned bonus for a

fiscal year of the Company following certification of the same by the Compensation Committee so long as you remain actively employed by the Company on the payment date for such bonus.

c. Long-Term Incentive. You will be eligible to receive long-term equity incentive awards pursuant to the terms of the Longeveron 2021 Incentive Award Plan (the "2021 Plan") (or any successor plan thereto). Initial long-term equity incentive awards will be granted in accordance with Appendix A attached hereto and incorporated herein. Additional long-term incentive awards may be granted at the discretion of the Compensation Committee and in accordance with market guidelines for your role as approved by the Compensation Committee.

d. Benefits. During your employment with the Company, you will be eligible for participation in employee health and welfare benefits programs, retirement programs, and other fringe benefits maintained by the Company, to the extent consistent with applicable law and the terms of the applicable plans and programs available to similarly situated executives of the Company. The Company retains all rights to amend or terminate any such benefit plans and programs, subject to the terms of such employee benefit plans and programs and applicable law, and nothing contained herein shall obligate the Company to continue any benefit plans or programs in the future. You will be eligible to receive vacation in accordance with the terms of the Company's vacation/Paid Time Off "PTO" policy.

e. Business Expenses. During the Term, the Company will reimburse you for reasonable business expenses, including travel, entertainment, and other expenses (including a mobile phone and data service) incurred by you in the furtherance of the performance of your duties hereunder, in accordance with the Company's Travel and Entertainment policy as in effect from time to time.

f. All payments made under this Agreement shall be reduced by any tax or other amounts required to be withheld under applicable law.

g. Place of Duty; You will be allowed to work from your current residence in California as long as you are present in Miami for business needs and as required by the job. You will be reimbursed for reasonable travel expenses in accordance with the Company's typical reimbursement practices.

4. Termination and Severance.

a. Upon your termination of employment for any reason, the Company shall pay to you (i) your base salary earned through the date of such termination, (ii) amounts for accrued but unused vacation days, (iii) all compensation and employee benefits, if any, that are due and owing to you under the terms of the Company's employee benefit plans and programs, in each case, in accordance with and subject to the terms and conditions of the applicable employee benefit plan, and (iv) any unreimbursed business expenses to which you would be entitled in accordance with the Company's reimbursement policy, not later than thirty (30) business days after the customary documentation regarding such expenses has been received and only to the extent that such expenses are submitted within one year of your termination (collectively, "Accrued Amounts"). For avoidance of doubt, your rights and obligations with respect to equity awards, if any, shall be controlled by, and subject to, the terms and conditions set forth in the 2021 Plan and the applicable award agreements.

b. In the event your employment is terminated during the Term by the Company without Cause (as defined below) or by you for Good Reason (as defined below), in addition to the Accrued Amounts, you will be entitled to receive, subject to your timely execution and non-revocation of a Release (as defined below) (i) any earned but unpaid bonus for any prior completed fiscal year, payable when such payments would otherwise be paid, (ii) a cash payment equal to severance benefits in the amount of three (3) months of your then existing Base Salary for every year you have worked full time for Longeveron (which, for the avoidance of doubt, commenced on March 1, 2023, and prorated for partial years, provided, however, that in no case shall the severance benefit under this section be less than twelve (12) months of your then existing Base Salary payablein one lump sum; and (iii) if you are eligible for and timely elect to continue health benefits under COBRA, the Company will pay the applicable COBRA premiums until the earlier of twelve eighteen (18) months following your termination date, the date you cease to be eligible for COBRA continuation coverage, or the date you become eligible for substantially equivalent health coverage from another employer, and (iv) annual cash bonus payment for current year, at target level and prorated based on date of termination.

c. Notwithstanding the foregoing, upon a termination of your employment by the Company without Cause or by you for Good Reason within six (6) months following a Change in Control (as defined in the 2021 Plan), in addition to the Accrued Amounts, you will be entitled to receive, subject to your timely execution and non-revocation of a Release (i) a lump sum payment equal to the sum of twelve (12) months of your base salary as of immediately prior to the Change in Control and 100% of your then-current annual cash bonus (at target level), (ii) if you are eligible for and timely elect to continue health benefits under COBRA, the Company will pay the applicable COBRA premiums until the earlier of twelve (12) months following your termination date, the date you cease to be eligible for COBRA continuation coverage, or the date you become eligible for substantially equivalent health coverage from another employer and (iii) full vesting of any equity awards then outstanding held by you (with any performance-based equity awards vesting at "target" levels) and the exercise period of any stock option continuing for a one-year period following your termination of employment. Notwithstanding anything to the contrary set forth herein, to the extent that there is a conflict between any of the terms set forth in this Agreement and any terms set forth in an award agreement relating to the grant of equity awards to you, the terms of this Agreement shall prevail.

d. In the event that your employment is terminated by the Company for Cause, or on account of your death, Disability or voluntary resignation, other than for reasons described in subsection (b) above, other than the amounts specified in subsection (a) above, you will not be entitled to receive any payments under this Agreement.

e. Payment of any severance payments or benefits pursuant to subsection (b) above is expressly conditioned upon your (i) execution of a general waiver and release of claims in such form and substance as reasonably required by the Company (the "Release"), within twenty-one (21) days of your termination unless additional time is required by law, and the Release becoming effective upon the expiration of the revocation period (which is seven days after the Release is executed and returned to the Company) and (ii) continued compliance with this Agreement and the Covenant Agreement (as defined below). If an executed Release is not returned to the Company within twenty-one (21) days of termination unless additional time is required by law or the Release is revoked by you, the Company shall be relieved of all obligations to pay you severance under this Agreement. The payment described in subsection 4(b)(ii) shall be paid in the form of salary continuation and shall be made in substantially equal installments, at least monthly, commencing on or before the 60th day following your termination date. The first such payment shall include payment of all severance benefits that otherwise would have been due prior to such date, applied as though such payments commenced on the next normal pay date immediately following your termination date. The payment described in subsection 4(b)(iv) and subsection 4(c)(i) shall be paid on or before the 60th day following your termination date.

f. For purposes of this Agreement:

"***Cause***" shall include, but not be limited to: (i) the executive's unauthorized use or disclosure of confidential information or trade secrets of the Company or any subsidiary, or any material breach of a written agreement between the executive and the Company or any of its subsidiaries, including without limitation a material breach of any employment, confidentiality, non-compete, non-solicit or similar agreement; (ii) the executive's commission of, indictment for or the entry of a plea of guilty or *nolo contendere* by the executive to, a felony under the laws of the United States or any state thereof or any crime involving dishonesty or moral turpitude (or any similar crime in any jurisdiction outside the United States); (iii) the executive's gross negligence or willful misconduct which is injurious to the Company or any of its subsidiaries, or the executive's willful or repeated failure or refusal to substantially perform assigned duties; (iv) any act of fraud, embezzlement, material misappropriation or dishonesty committed by the executive against the Company or any of its subsidiaries; (v) the material violation by the executive of any rule or policy of the Company or any of its subsidiaries of which the executive had written notice; or (v) any acts, omissions or statements by a executive which the Company reasonably determines to be materially detrimental or damaging to the reputation, operations, prospects or business relations of the Company or any subsidiary.

"***Good Reason***" means (i) a change in the executive's position with the Company that materially reduces the executive's authority, duties or responsibilities or the level of management to which he or she reports, (ii) a material diminution in the executive's level of compensation (including base salary, fringe benefits and target bonuses under any corporate performance-based incentive programs), excluding any reduction that applies generally to similarly situated employees of the Company, and excluding any change made in connection with the termination of your employment for Cause, or on account of your death or Disability, or temporarily as a result of your Disability or other absence for an extended period; *provided*, that you will not have the right to resign for Good Reason pursuant to this provision of the

Good Reason definition due to a change in authority, duties or responsibilities solely as a result of the Company no longer being a publicly traded company,, provided further, that Good Reason shall not be deemed to exist unless (A) the executive provides written notice to the Company of the event giving rise to Good Reason within thirty (30) days of the occurrence of such event (setting forth the nature of such event and the corrective action reasonably sought by the executive); (B) the Company fails to cure the event giving rise to Good Reason within forty-five (45) days after written notice thereof is given by the executive to the Company (the "Cure Period"); and (C) the executive terminates the executive's service within thirty (30) days following the last day of the Cure Period.

g. Effective as of the date of your termination of employment, unless otherwise requested by the Company in writing, you will, automatically and without further action on your part or any other person or entity, resign from all offices, boards of directors (or similar governing bodies) and committees of the Company. You agree that you will, at the request of the Company, execute and deliver such documentation as may be required to effect such resignations, and authorize any member of the Company to file (or cause to be filed) such documentation, as necessary, with any applicable governmental authority.

h. In consideration for the promises and payments by the Company pursuant to this Agreement, at the request of the Company, for a one-year period following your termination of employment for any reason, you agree to cooperate to the fullest extent possible with respect to matters involving any member of the Company about which you have or may have knowledge, including any such matters which may arise before or after the Term; *provided* such cooperation shall not unreasonably interfere with any obligations you may have to your current employer at the time. The Company will compensate you for your time at a reasonable rate to be agreed to, reimburse you for any reasonable, properly documented out-of-pocket expenses, including your travel expenses and attorneys' fees that you actually incur in connection with such cooperation.

i. The Company shall provide Director and Officers (D&O) insurance coverage from the start date of employment in accordance with its existing policies. In addition, you will be eligible to sign a stand-alone indemnification agreement in form and substance the same as other Directors and Executive Officers.

5. **Section 409A**. This Agreement is intended to comply with Section 409A of the Code ("Section 409A") or an exemption thereunder and shall be administered and interpreted accordingly. Each payment under this Agreement, including each installment payment, shall be considered a separate and distinct payment. For purposes of this agreement, each payment is intended to be excepted from Section 409A to the maximum extent provided as follows: (i) each payment made within the applicable 2½ month period specified in Treas. Reg. § 1.409A-1(b)(4) is intended to be excepted under the short-term deferral exception; (ii) post-termination medical benefits are intended to be excepted under the medical benefits exceptions as specified in Treas. Reg. § 1.409A- 1(b)(9)(v)(B); and (iii) to the extent payments are made as a result of an involuntary separation, each payment that is not otherwise excepted under the short-term deferral exception or medical benefits exception is intended to be excepted under the involuntary pay exception as specified in Treas. Reg. § 1.409A-1(b)(9)(iii). With respect to any payment subject to Section 409A (and not excepted therefrom), if any, it is intended that each payment is paid on a permissible distribution event and at a specified time consistent with Section 409A. You shall have no right to designate the date of any payment under this Agreement. In the event the terms of this Agreement would subject you to the imposition of taxes and penalties under Section 409A ("409A Penalties"), the Company and you shall cooperate diligently to amend the terms of this Agreement to avoid such 409A Penalties, to the extent possible; *provided* that, for the avoidance of doubt, you shall be solely liable for any 409A Penalties incurred by you.

All references in this Agreement to your termination of employment shall mean your "separation from service" within the meaning of Section 409A of the Code and Treas. Reg. § 1.409A-1(h). Whether you have had a separation from service will be determined based on all of the facts and circumstances and in accordance with the guidance issued under Section 409A.

Notwithstanding any other provision of this Agreement to the contrary, if any payment or benefit provided to you in connection with your termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are determined by the Company to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date following the six-month anniversary of your termination date or, if earlier, on your death (the "Delayed Payment Date"). The aggregate of

any payments that would otherwise have been paid before the Delayed Payment Date shall be paid (without interest) to you (or your estate or beneficiaries) in a lump sum on the Delayed Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

With respect to any taxable expense reimbursements , in-kind benefits and/or cash allowances provided or paid by the Company under this Agreement, such reimbursement shall be made in accordance with and subject to the following terms and conditions: (i) reimbursements shall only be made to the extent that the expense was actually incurred and reasonably substantiated; (ii) reimbursements of eligible expenses shall be made on or before the last day of your taxable year following the taxable year in which you incurred the expense; (iii) the amount of any expenses eligible for reimbursement or the amount of any in-kind benefits provided, as the case may be, under this Agreement during any calendar year shall not affect the amount of expenses eligible for reimbursement or the amount of any in-kind benefits provided during any other calendar year; and (iv) the right to reimbursement or to any in-kind benefit pursuant to this Agreement shall not be subject to liquidation or exchange for any other benefit.

Notwithstanding any provision of this Agreement to the contrary, you acknowledge and agree that the Company and its employees, officers, directors and affiliates are not providing you with any tax advice with respect to Section 409A of the Code or otherwise and are not making any guarantees or other assurances of any kind to you with respect to the tax consequences or treatment of any amounts paid or payable to you under this Agreement. Nothing provided or contained in this Agreement will be construed to obligate or cause the Company and/or its employees, officers, directors, subsidiaries and affiliates to be liable for, any tax, interest or penalties imposed on you related to or arising with respect to any violation of Section 409A.

6. **Section 280G**. If the present value of your severance benefits, either alone or together with other payments which you have the right to receive from the Company (the "Benefits") constitute a "parachute payment" as defined in Section 280G of the Code, then your Benefits shall be either (i) provided to you in full, or (ii) provided to you only as to such lesser extent that would result in no portion of such Benefits being subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), whichever of the foregoing amounts, taking into account the applicable federal, state, and local income and employment taxes and the Excise Tax, results in the receipt by you, on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such Benefits may be taxable under the Excise Tax.

Unless the Company and you otherwise agree, any determination required under section shall be made in writing in good faith by the Company's independent accounting firm or such other nationally or regionally recognized accounting firm selected by the Company (the "Accountants"), whose determination shall be conclusive and binding upon you and the Company for all purposes. In the event that a reduction to the Benefits under this section, the reduction shall apply first to the Benefits that are not deferred compensation subject to Section 409A of the Code and you shall be given the choice, subject to approval by the Company, of which of such Benefits to reduce; provided, that such reduction achieves the result specified in clause (ii) above of this section. If a reduction in the Benefits that are subject to Section 409A of the Code is required, such Benefits shall be reduced pro rata, but with no change in the time at which such Benefits shall be paid. For purposes of making the calculations required by this section, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Code. The Company and you shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this section.

7. **Restrictive Covenant Obligations**. You acknowledge and agree that you will be subject to the Company's existing policies regarding confidentiality, non-disclosure, non-use, non-competition, non-solicitation or other covenants pursuant to the terms of that certain Confidentiality and Nondisclosure agreement with the Company, which shall be executed prior to the Effective Date (the "Covenant Agreement"). Notwithstanding any provision in this Agreement, the Covenant Agreement or otherwise to the contrary, nothing in this Agreement, the Covenant Agreement or otherwise precludes or otherwise limits your ability to (A) communicate directly with and provide information, including documents, not otherwise protected from disclosure by any applicable law or privilege to the Securities and Exchange Commission (the "SEC") or any other federal, state or local governmental agency or commission ("Government Agency") or self-regulatory organization regarding possible legal violations, without disclosure to the Company, or (B) disclose information which is required to be disclosed by applicable law, regulation, or order or requirement (including without

limitation, by deposition, interrogatory, requests for documents, subpoena, civil investigative demand or similar process) of courts, administrative agencies, the SEC, any Government Agency or self-regulatory organizations, provided that, if permissible by law, you provide the Company with prior notice of the contemplated disclosure and cooperate with the Company in seeking a protective order or other appropriate protection of such information. The Company may not retaliate against you for any of these activities.

8. **Representation Regarding Prior Commitment**. You represent that your performance of all of the terms of this Agreement and the performance of the services for the Company does not and will not breach or conflict with any agreement with a third party, including an agreement not to compete or to keep in confidence any proprietary information of another entity acquired by you in confidence or in trust prior to the date of this Agreement. You agree that you will not enter into any agreement that conflicts with this Agreement during the term of your employment with the Company.

9. **Governing Law, Forum and Venue**. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the State of Florida, without reference to the principles of conflicts of law or choice of law of the State of Florida, or any other jurisdiction, and where applicable, the laws of the United States. All questions pertaining to the validity, construction, execution and performance of this Agreement shall be construed and governed in accordance with the laws of the State of Florida, without giving effect to principles of conflicts or choice of law. Jurisdiction and venue for any disputes shall be, as appropriate, in the state courts in Miami-Dade County, FL, or the federal courts in the Southern District of Florida.

EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHTS TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

10. **Validity**. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect. You were advised to seek counsel with regard to this Agreement and all employment terms, and you were represented by counsel.

11. **Final Agreement**. The terms of this Agreement and the Covenant Agreement are intended by the parties to be the final expression of their agreement with respect to your employment by the Company and supersede, effective as of the Effective Date, all prior understandings and agreements with respect to your employment by the Company, whether written or oral. For the avoidance of doubt, if the Effective Date does not occur, this Agreement will be void *ab initio*. Any other signed written agreements, including referenced herein that are not in contradiction with this Agreement are in full force and effect.

12. **Assignment**. The rights and benefits under this Agreement are personal to you and such rights and benefits shall not be subject to assignment, alienation or transfer, except to the extent such rights and benefits are lawfully available to your estate or any of your beneficiaries upon your death. The Company may assign this Agreement to any affiliate or subsidiary at any time and shall require any entity which at any time becomes a successor, whether by merger, purchase, or otherwise, or otherwise acquires all or substantially all of the assets, membership interests or business of the Company, to expressly assume this Agreement.

13. **Counterparts**. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile shall be deemed effective for all purposes.

[Signature page follows]

Please sign and date this Agreement in the space indicated and return it to my attention to evidence your understanding and acceptance of the terms set forth herein.

Sincerely,

Longeveron Inc.

By: /s/ Joshua Hare
Name: Joshua Hare

Position: Chairman, Chief Science Officer

Agreed to and Accepted:

/s/ Wa'el Hashad
Name: Wa'el Hashad

Appendix A
Long-Term Incentive Equity Awards

For so long as employee remains employed as Chief Executive Officer (CEO), he will be entitled to receive the following equity incentive awards:

1. Upon the Effective Date of employment as CEO, he will receive an award of 50,000 Restricted Stock Units (RSUs), which shall vest in four quarterly installments on each of April 1, July 1, September 1 and December 31, 2023.

2. For each of calendar 2023, 2024, 2025 and 2026, CEO will receive, in accordance with the grant schedule established by the Compensation Committee and commensurate with other executive officers, the following equity awards:

a. Stock Option Award, exercisable for 50,000 shares of common stock. The Award will have time-based vesting, and will vest 100% on the first anniversary of the date of grant.

b. 125,000 Performance Share Units (PSUs). The performance metrics applicable to earn the PSUs will be established annually by the Compensation Committee and communicated to the award recipient at the time of grant. The PSU awards will be structured to allow for partial satisfaction and payment of award, with a minimum "floor" of 25,000 PSUs to be paid so long as CEO remains employed on the date of payout. Payout of PSU awards shall occur no later than the end of the first quarter following the year of grant, following certification by the Compensation Committee of the degree to which the applicable performance criteria have been met.

EXHIBIT 19.1

STATEMENT OF POLICY ON INSIDER TRADING

INTRODUCTION

It is the policy of Longeveron Inc. (collectively any present or future subsidiaries, the "Company") that its employees, consultants and members of its Board of Directors ("Company Personnel") comply fully with the insider trading securities laws and regulations of the United States. Company Personnel must maintain a basic familiarity with the principles and purposes of these laws as they may be applied to the Company and avoid any activity that might violate these laws or give any appearance either of violation or intention to violate. Compliance with this Statement of Policy on Insider Trading (this "Policy") defines the scope of employment for Company employees. Conduct that violates or does not comply with this Policy is outside the scope of employment for Company employees. Any employee who fails to comply with this Policy will be subject to appropriate disciplinary action, which may include suspension or termination.

This Policy is not a description of all applicable securities statutes, but rather is intended to set forth a course of conduct and guiding principles designed to ensure that the employees and directors of the Company do not engage in any activity that violates the spirit of the insider trading provisions of the securities laws, is unfair to the Company's public stockholders or other stakeholders, or creates an appearance of a violation.

PERSONS SUBJECT TO THE POLICY

Part I of this Policy applies to all members of the Company's Board of Directors and to all of the Company's employees and consultants. We refer collectively to those covered by this Policy as "Company Personnel". The Company may also determine that other persons should be subject to this Policy, such as contractors or consultants who have access to material nonpublic information. This Policy also applies to family members, other members of a person's household and entities controlled by a person covered by this Policy, as described below.

In addition, certain Company Personnel are subject to additional guidelines as it relates to transactions in the Company's securities, as outlined in Part II of this Policy. If your job title or category is listed on ***Schedule A***, then the additional requirements set forth in Part II of this Policy apply to you.

If you are unsure as to whether you are subject to the additional guidelines set forth in Part II of this Policy, please contact the Company's General Counsel or Chief Financial Officer to discuss.

PART I

This Policy applies to the following categories of securities (collectively, they are referred to as the "**Securities**"):

- Company Securities. This includes the Company's common stock (NASDAQ: LGVN), Class B common stock, options to purchase common stock, restricted common stock, restricted stock units, or any other type of securities that the Company may issue, including derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to Company Securities; and

- Securities of Companies with whom the Company Transacts Business. This would include securities of any company about which you have material, nonpublic information that you obtained through or in connection with your employment with or work at Longeveron. We refer to those companies in this Policy as "**Associated Companies**".

POLICY:

NO TRADING ON OR TIPPING OF MATERIAL NONPUBLIC INFORMATION

1. No Company Personnel may trade, directly or indirectly through family members or other persons or entities in Company Securities if they are aware of material nonpublic information (except as set forth under "***Transactions For Which this Policy Does Not Apply***")

2. No Company Personnel may recommend the purchase or sale of any Company security or disclose such information to others to others who might use it for trading or might pass it along to others who might trade. This practice, known as "tipping," also can result in same penalties as trading even though you did not trade and did not gain any benefit from another trader

3. No Company Personnel may disclose material nonpublic information to persons outside of the Company, including, but not limited to, family, friends, business associates, investors, or other third parties, unless the disclosure is made in accordance with the Company's policies.

4. Company Personnel may not trade, directly or indirectly, through family members or other persons or entities, in securities of any other organization (including, without limitation, an Associate Company) unless they are sure they do not possess any material nonpublic information about the organization which they obtained in the course of their employment with the Company, such as information about a major contract being negotiated. Information that is not material to the Company may nevertheless be material to the other organization.

5. No Company Personnel may assist anyone engaged in any of the above activities.

It is also important that when you disclose material nonpublic information to persons within the Company you do so in a manner that is consistent with directives and the confidentiality restrictions that have been provided to you with that information.

CONSEQUENCES FOR VIOLATION

The purchase or sale of Securities (including Company Securities) while aware of material, nonpublic information with respect to the issuer of such securities, or the disclosure of material, nonpublic information to others who then trade in Securities of such issuer (including Company Securities), is prohibited by federal and state laws. Insider trading violations are pursued vigorously by the U.S. Securities and Exchange Commission (the "SEC"), U.S. Attorneys and state enforcement authorities, as well as the laws of foreign jurisdictions. Punishment for insider trading violations is severe and could include significant fines and imprisonment. While the regulatory authorities concentrate their efforts on the individuals who trade, or who tip inside information to others who trade, the federal securities laws also impose potential liability on companies and other "controlling persons" if they fail to take reasonable steps to prevent insider trading by company personnel.

U.S. securities laws impose severe penalties for trading on material non-public information and communicating knowledge of material, non-public information to another person or company (other than in the necessary course of business) who thereafter purchases or sells securities, which can include disgorgement of the unlawful profits, civil penalties of up to three

times the profit gained or loss avoided, criminal fines of up to $5,000,000 and/or jail terms of up to 20 years. Similar legislation imposes similar penalties in other jurisdictions.

In addition, an individual's failure to comply with this Policy may subject the individual to Company- imposed sanctions, including dismissal for cause, whether or not the failure to comply results in a violation of law. Needless to say, a violation of law, or even an investigation by the SEC that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career. This Policy sets forth the Company's policy against insider trading. **All Company Personnel must comply with this Policy.** There are no exceptions to this Policy, except as specifically noted herein. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, **are not excepted from this Policy.** The securities laws do not recognize any mitigating circumstances, and in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

DEFINITIONS

Material Information: All information that a reasonable investor would consider important in deciding whether to buy, sell, or hold Securities is considered material. As it relates to Company Securities, information that could be expected to affect the Company's stock price, whether it is positive or negative, should be considered material. There is no "bright line" standard for assessing materiality; rather, materiality is based on an assessment of all facts and circumstances and is often evaluated by enforcement authorities with the benefit of hindsight. Examples of some types of material information are: (i) trial or study results, or other information regarding the efficacy or safety of the Company's products; (ii) financial results for the quarter or the year; (iii) financial forecasts, projections or other information, including projection of earnings (or other financial metrics) or other types of financial guidance; (iv) changes to previously announced earnings (or other financial metrics) guidance; (v) possible mergers, acquisitions, joint ventures, and other purchases and sales of companies and investments in companies; (vi) obtaining or losing important contracts, licenses, or regulatory approvals; (vii) information about vendor relationships; (viii) major financing developments (including new equity, debt or bank financings or grants); (ix) major personnel changes; (x) major litigation developments; (xi) the establishment of a repurchase program for Securities; (xii) changes in the Company's auditors or a notification from its auditors that the Company may no longer rely on the auditors' audit report; (xiii) the imposition of a trading ban on Company Securities or the securities of another company; (xiv) major events regarding Company Securities; and/or (xv) changes in dividends or to a dividend policy.

UNAUTHORIZED DISCLOSURE OF MATERIAL, NONPUBLIC INFORMATION PROHIBITED

General Rule. No Director, Officer or Employee may disclose material, nonpublic information about Longeveron or any company with which Longeveron deals to anyone, unless such disclosure is in the necessary course of business. Questions regarding what constitutes disclosure in the necessary course of business shall be decided by the General Counsel and/or the Chief Financial Officer.

Tipping. Under the U.S. federal securities laws, you can be held responsible not only for your own insider trading, but also for securities transactions by anyone to whom you disclose material, nonpublic information. Even if those to whom you disclose such information do not trade while aware of the information, you can be responsible for the trades of persons who received material, nonpublic information indirectly from you, if you are the ultimate source of their information.

Discussing or Recommending Longeveron Securities. We recognize that employee enthusiasm for Longeveron and its business prospects is a vital element of our success. You should, however, use extreme caution when discussing our business or our securities with anyone. In the course of discussing our business or our securities, accidental disclosure of material, nonpublic information can occur and can be viewed as "tipping." Likewise, recommendations of our securities can also result in embarrassing situations for you or the Company if you make a recommendation at a time when there is a pending announcement of material, nonpublic information by the Company, even if you are unaware of that information.

Chat Rooms and Internet Postings. No Director, Officer or Employee may disclose information about Longeveron' or its securities on the Internet (regardless of whether such information is material or already public), and, more specifically, in discussion forums or chat rooms where companies and their prospects are discussed. Messages in these forums are typically made by unsophisticated investors who are sometimes poorly informed, and generally are carelessly stated or, in some cases, malicious or manipulative and intended to benefit their own stock positions. In addition, disclosures of material nonpublic

information through this type of forum may amount to a "tip" or leak of such information, in violation of this Policy and applicable law. Accordingly, no Director, Officer or Employee of Longeveron may discuss the Company or Company-related information in such a forum, regardless of the situation. Despite any inaccuracies that may exist in these forums, postings in these forums can result in the disclosure of information that may be harmful to the Company and expose you to liability for violating U.S. federal securities laws.

Employees and/or Contracted Employees who encounter a discussion pertaining to the Company in such forums should advise the General Counsel immediately, so the discussion may be monitored.

Authorization to Disclose Material, Nonpublic Information Outside the Company. We authorize only certain Directors and Officers to make public disclosures of material, nonpublic information or to confer with persons outside the Company regarding such information (for example, our auditors, outside counsel and other advisors). Unless you are authorized to do so by the CEO, the President, the CFO or the General Counsel, you should refrain from discussing material, nonpublic information with anyone not in the Company. Even in discussions with others subject to this Policy, you should consider the consequences of disclosing material, nonpublic information to them. For example, by doing so, you would preclude those persons from trading in Longeveron' securities until the information is publicly disclosed. Accordingly, you should restrict the communication of material, nonpublic information to those Directors, Officers or Employees and/or Contracted Employees having a need to know in order to serve Longeveron' interests.

Sele*ctive Disclosure.* There are SEC rules and regulations banning selective disclosure of information relating to public companies. Generally, these regulations provide that when a public company (such as Longeveron) discloses material, nonpublic information, it must provide broad, non-exclusionary public access to the information (for example, through press releases, conference calls or webcasts). Violations of these regulations can result in enforcement actions, resulting in injunctions and severe monetary penalties. The Company's Disclosure Policy provides that a limited group of senior Officers and Directors are the only Company personnel authorized to communicate information regarding the Company with securities market professionals, shareholders or members of the media. Such persons are aware of the rules and regulations banning selective disclosure and have been trained in how to comply with such rules and regulations. No other Longeveron Directors, Officers or Employees and/or Contracted Employees are authorized to communicate information regarding the Company with securities market professionals, shareholders or members of the media because of the risk that such communications might violate the ban on selective disclosure.

Non-Disclosure Agreements. Directors, Officers or Employees and/or Contracted Employees involved in transactions or other negotiations that require disclosure of material, nonpublic information with parties outside Longeveron should generally have those to whom such information is being disclosed sign a non-disclosure agreement. The non-disclosure agreement will require that the recipient of information not disclose the information to others, other than in the necessary course of business, and require the recipient not to trade in Longeveron securities while in possession of such information. You should confer with the General Counsel whenever a non- disclosure agreement may be needed.

Information that is likely to affect the price of Securities is almost always material.

Non-Public Information: Information is considered to be nonpublic **unless** it has been effectively disclosed to the public by the Company. Examples of effective disclosure include public filings with the SEC, Company press releases, Company meetings with members of the press and the public dissemination of information through Dow Jones "broad tape," news wire services, broadcast on widely- available radio or television programs, and publications in widely available newspapers, magazines or news websites. By contrast, information would likely not be considered widely disseminated if it is available only to Company Personnel, or if it is only available to a select group of analysts, brokers or institutional investors. The information must not only be publicly disclosed; there must also be adequate time for the market as a whole to digest the information. Generally, at least one full trading day of general availability may be required for information to be considered public. For example, if the Company were to make an announcement of material information on a Monday at 8:00 a.m. (local time), you should not trade in Company Securities until Tuesday at 8:00 a.m. (local time). Depending on the particular circumstances, the Company may determine that a longer or shorter period should apply to the release of specific material nonpublic information.

OTHER PROHIBITED TRANSACTIONS

Due to recent developments and legal changes, the Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. It therefore is the Company's policy that Company Personnel may not engage in any of the following transactions without first consulting with and obtaining clearance from the Company (which clearance may be denied for any reason): (i) short sales; (ii) publicly-traded options, (iii) hedging transactions (including prepaid variable forwards, equity swaps, collars and exchange funds), (iv) margin accounts and pledged securities; and (v) standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans).

ADDITIONAL GUIDANCE

Transactions by Family Members and Others. This Policy applies to (i) your family members who reside with you, (ii) anyone else who lives in your household, (iii) any family members who do not live in your household but whose transactions in Company Securities are directed by you or are subject to your influence or control ((i), (ii) and (iii) collectively, "Family Members"), and (iv) any entities that you influence or control, including any corporations, partnerships or trusts. You are responsible for the transactions of these other persons or entities and therefore should make them aware of the need to confer with you before they trade in Company Securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account. However, this Policy does not apply to personal securities transactions of Family Members where the investment decision is made by a third party not controlled by, influenced by or related to you or your Family Members.

Transactions For Which this Policy Does Not Apply. This Policy does not apply in the case of the following transactions, except as specifically noted (collectively referred to as "Excepted Transactions"):

Stock Option Exercises Where No Sale is Made. This Policy does not apply to the exercise of a stock option acquired pursuant to the Company's plans, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements; **however**, this Policy does apply to any sale of stock as part of a broker assisted cashless exercise of an option, or any other market sale related to an option exercise, whether for the purpose of generating the cash needed to pay the exercise price of an option, to satisfy tax withholding requirements or otherwise.

Restricted Stock Awards. This Policy does not apply to the vesting of restricted stock, or the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock; **however**, this Policy does apply to any market sale or other disposition of restricted stock.

Bona Fide Gifts of Securities. Gifts of securities are not transactions subject to this Policy, unless the person making the gift has reason to believe that the recipient intends to sell the Securities while the person making the gift is aware of material, nonpublic information.

Rule 10b5-1 Plans Approved in Accordance with this Policy. Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a plan for transactions in Company Securities that meets the requirements of Rule 10b5-1 (a "Rule 10b5-1 Plan"). Under a Rule 10b5-1 Plan, Company Securities may be purchased or sold without regard to certain insider trading restrictions. To comply with this Policy, a Rule 10b5-1 Plan must be approved by the General Counsel and the Chief Financial Officer and meet the requirements of Rule 10b5-1.

Mutual Fund Transactions. Transactions in mutual funds that are invested in Company Securities are also not subject to this Policy.

Dividend Reinvestment. Currently the Company does not maintain a Company sponsored dividend reinvestment plan; however, if you choose through your broker or another third party to participate in a non-Company sponsored dividend reinvestment program, then, so long as you enter such a program at a time when you are not aware of material nonpublic information concerning the Company, your participation in such a program and the purchases of Company Securities under the program are not subject to this Policy. Nevertheless, this Policy applies to your sale or other disposition of any Company Securities purchased pursuant to such a program.[1]

Post-Termination Transactions. Because the prohibitions on insider trading are mandated in the law, the restrictions contained in this Policy continue to apply to you even after termination of your service with the Company. You will be solely responsible for complying with these requirements after your service with the Company is over. If an individual is in possession of material, nonpublic information regarding the Company or another company when his or her service terminates, that individual may not trade in Company Securities or securities of such other company until that information has become public or is no longer material in accordance with this Policy.

[1] Any person subject to Section 16 under the Exchange Act should be aware that acquisitions of Company Securities made through non-Company sponsored dividend reinvestment programs are not exempt from Section 16(b) of the Exchange Act and those acquisitions are potentially matchable with any non-exempt "opposite-way" disposition transactions within the past six months. As such, Section 16 officers and members of the Board of Directors are strongly discouraged from participating in non-Company sponsored dividend reinvestment programs.

PART II

Additional Provisions of this Policy that Apply to Certain Company Personnel Only

IN ADDITION TO THE GENERAL REQUIREMENTS OF THIS POLICY THAT ARE APPLICABLE TO ALL COMPANY PERSONNEL, THERE ARE SPECIAL ADDITIONAL REQUIREMENTS THAT ARE APPLICABLE TO SPECIFIC GROUPS OF COMPANY PERSONNEL. IF YOU ARE IN ONE OF THE CATEGORIES OF COMPANY PERSONNEL THAT HAVE THESE ADDITIONAL RESTRICTIONS THEN YOU MUST COMPLY WITH THESE ADDITIONAL RESTRICTIONS.

A. Trading Blackout Periods Which is Applicable Only To "Designated" Persons

Certain employees and advisors routinely possess or have access to material, nonpublic information and those job titles or categories are listed on ***Schedule A*** hereto (collectively, the "**Designated Persons**"). The trading window portion of this Policy applies to transactions by Designated Persons in Company Securities.

As more fully described below, Designated Persons are prohibited from engaging in transactions involving Company Securities during the Blackout Period. The "Blackout Period" means (i) the period commencing on the calendar day marking the end of any fiscal quarter (including the end of the fiscal year) and ending two full trading days after the Company's earnings release has been made public for that period and (ii) any other period deemed a "Blackout Period" that is event driven, as described below.

For purposes of illustration only, if the Company's fiscal quarter ended on September 30 (i.e. the last day of the fiscal quarter is September 30, and the next quarter started October 1), the Blackout Period would be in effect starting at 12:01 a.m. on September 30 and would end two full trading day following the Company's earnings release for that quarter.

In addition to the quarterly Blackout Periods set forth above, from time to time an event may occur that is material to the Company and is known by only select directors, officers or employees. In that situation, the Chief Executive Officer, Chief Financial Officer, General Counsel or their designees will notify these select persons that they should not trade in Company Securities; provided, however, that if you are not specifically notified by the Company of an event-specific Blackout Period, but nevertheless are in possession of material, nonpublic information, you should refrain from trading until such information becomes public in accordance with Part I of this Policy. The existence of an event-specific Blackout Period generally will not be announced to the Company as a whole and should not be communicated to any other person. The appropriate officers of the Company or their designees will provide additional notification when such event-specific Blackout Period is lifted.

These prohibitions shall not apply to any Excepted Transactions (as defined in Part I of this Policy); however, the prohibition on engaging in transactions in Company Securities does extend to and shall preclude any such Designated Persons from engaging in transactions other than Excepted Transactions.

B. Pre-Clearance Policy Applicable To Designated Persons

Company Personnel who are Designated Persons are also required to pre-clear any trades in Company Securities. (See Pre- Clearance Request Form on the last page).

All Designated Persons are required to (i) provide the Company written notice of any proposed transaction in Company Securities and (ii) receive clearance prior to entering into that proposed transaction, in each case as set forth below.

To prevent inadvertent violations of this Policy and to avoid even the appearance of an improper transaction (which could result, for example, where a Designated Person engages in a transaction while unaware of a pending major development), any Designated Person who proposes to undertake a transaction in Company Securities, which includes any acquisition, disposition or other transfer for value, whether through the Company's stock plan administrator or another broker (other than Excepted Transactions), must obtain pre-clearance through the following process:

Step One: Provide a written request for clearance to transact in Longeveron securities, which request must provide all relevant information needed for the Company to assess said request.

Step Two: Email the request to the Chief Financial Officer or General Counsel.

Step Three: Approval for your request will be solicited from the Company's Chief Executive Officer, Chief Financial Officer or General Counsel. Notice of approval (or denial if applicable) will be communicated back to you via email.

Step Four: If approved, unless otherwise determined by the General Counsel's office, you will have until the earlier of (i) five (5) trading days from the date of approval (inclusive of the date you receive approval) and (ii) the commencement of a Blackout Period (the "Open Period") to conduct your transaction(s). After the Open Period expires, you must repeat the pre-clearance process (as outlined above) prior to conducting any further transactions. Any sell/buy orders that are outstanding as of the end of the Open Period must be cancelled unless you have requested and received approval for an additional Open Period in accordance with the procedures herein.

When a request for pre-clearance is made, the Designated Person should carefully consider whether he or she may be aware of any material, nonpublic information about the Company, as further discussed in this Policy, and should fully describe those circumstances in his or her request. If the Designated Person is subject to Section 16 under the Exchange Act, the Designated Person should also determine whether he or she has effected any non-exempt "opposite-way" transactions within the past six months, and should be prepared to review any Form 4 or Form 5 that will be required to be filed in connection with such transaction. The requestor should also be prepared to comply with SEC Rule 144 and file Form 144, if necessary, at the time of any sale.

Even though gifts of securities are not transactions subject to the Policy generally, as a best practice we encourage Designated Persons to provide prior notice of any gift transaction to the Chief Financial Officer and General Counsel. The Company makes this request because in some circumstances where a donor knows that a charitable gift recipient (usually a charitable organization) will typically sell the donated stock soon after the gift is made, any such sale that is made while the donor is aware of material non-public information could result in potential claims of conflict of interest and the appearance of impropriety.

In all cases, the ultimate responsibility for adhering to this Policy rests with you. Any action on part of the Company, the Company's Chief Executive Officer, Chief Financial Officer or General Counsel or any other employee or director pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws.

Your failure to observe this Policy could lead to significant legal problems, as well as having other serious consequences, including termination of your employment.

Policy Effective: February 12, 2021
Amended Effective: February 27, 2025

dfsfsd

STATEMENT OF POLICY ON INSIDER TRADING
(EFFECTIVE AS OF FEBRUARY 12, 2021; REVISED AS OF FEBRUARY 27, 2025)

SCHEDULE A
(DESIGNATED PERSONS)

1. Members of the Board of Directors

2. CEO, CFO, CSO, General Counsel

3. All Employees

4. Any other individual who may from time to time be designated as a Designated Person by the Chief Executive Officer or the General Counsel of the Company

PRE-CLEARANCE REQUEST FORM

TO: LONGEVERON, INC. (THE "COMPANY")

INSIDER TRADING COMPLIANCE OFFICER

GENERAL COUNSEL AND CHIEF FINANCIAL OFFICER

FROM:

RE: PROPOSED TRANSACTION IN THE COMPANY'S SECURITIES

THIS IS TO ADVISE YOU THAT THE UNDERSIGNED INTENDS TO EXECUTE A TRANSACTION IN THE COMPANY'S SECURITIES ON _____ _____, 20 _____ AND THEREAFTER UNTIL THE TRADING WINDOW SHALL CLOSE AND DOES HEREBY REQUEST THAT THE COMPANY PRE-CLEAR THE TRANSACTION AS REQUIRED BY THE COMPANY'S INSIDER TRADING POLICY (THE "POLICY").

THE GENERAL NATURE OF THE TRANSACTION IS AS FOLLOWS (I.E. OPEN MARKET PURCHASE OF 10,000 SHARES OF COMMON STOCK THROUGH NASDAQ, PRIVATELY NEGOTIATED SALE OF WARRANTS FOR THE PURCHASE OF 5,000 SHARES OF COMMON STOCK, ETC.):

THE UNDERSIGNED IS NOT IN POSSESSION OF MATERIAL NONPUBLIC INFORMATION (AS DEFINED IN THE INSIDER TRADING POLICY) ABOUT THE COMPANY AND WILL NOT ENTER INTO THE TRANSACTION IF THE UNDERSIGNED COMES INTO POSSESSION OF MATERIAL NONPUBLIC INFORMATION ABOUT THE COMPANY BETWEEN THE DATE HEREOF AND THE PROPOSED TRADE EXECUTION DATE.

THE UNDERSIGNED HAS READ AND UNDERSTANDS THE POLICY AND CERTIFIES THAT THE ABOVE PROPOSED TRANSACTION WILL NOT VIOLATE THE POLICY.

THE UNDERSIGNED AGREES TO ADVISE THE COMPANY PROMPTLY IF, AS A RESULT OF FUTURE DEVELOPMENTS, ANY OF THE FOREGOING INFORMATION BECOMES INACCURATE OR INCOMPLETE IN ANY RESPECT. THE UNDERSIGNED UNDERSTANDS THAT THE COMPANY MAY REQUIRE ADDITIONAL INFORMATION ABOUT THE TRANSACTION AND AGREES TO PROVIDE SUCH INFORMATION UPON REQUEST.

DATED: _____

VERY TRULY YOURS,

[SIGNATURE]	[PRINT NAME]

APPROVED: ***APPROVED:***

GENERAL COUNSEL	*CHIEF FINANCIAL OFFICER*

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Longeveron Inc. on Forms S-1 File Nos. 333-252234, 333-253029, 333-261667, 333-272946, 333-275578, 333-278073, 333-276745, 333-278995, 333-280577, and 333-281299, S-3 File No. 333-264142 and S-8 File Nos. 333-253141, 333-272938, and 333-280747 of our report dated February 28, 2025, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of Longeveron Inc as of December 31, 2024 and 2023 and for the years ended December 31, 2024 and 2023, which report is included in this Annual Report on Form 10-K of Longeveron Inc. for the year ended December 31, 2024.

/s/ Marcum LLP

Hartford, CT
February 28, 2025

Exhibit 31.1

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Wa'el Hashad, certify that:

1. I have reviewed this annual report on Form 10-K of Longeveron Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant 's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2025

/s/ Wa'el Hashad
Wa'el Hashad
Chief Executive Officer

Exhibit 31.2

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Lisa A. Locklear, certify that:

1. I have reviewed this annual report on Form 10-K of Longeveron Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant 's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2025

/s/ Lisa A. Locklear
Lisa A. Locklear
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO U.S.C. SECTION 1350
AS ADOPTED PURSANT TO SECTION 206 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Longeveron Inc. (the "Company") on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Wa'el Hashad, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2025

/s/ Wa'el Hashad
Wa'el Hashad
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO U.S.C. SECTION 1350
AS ADOPTED PURSANT TO SECTION 206 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Longeveron Inc. (the "Company") on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lisa A. Locklear, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2025

/s/ Lisa A. Locklear
Lisa A. Locklear
Executive Vice President and
Chief Financial Officer