2023 Annual Report

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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

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
Common Stock, par value $0.001	**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 $19,016,000 as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter).

As of February 23, 2024, the registrant had 10,294,603 shares of Class A common stock, $0.001 par value per share, and 14,839,993 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, ability to continue as a going concern and ability to remain listed on the Nasdaq Capital Market;
- 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 our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- 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., Japan, The Bahamas, 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. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein after we file this 10-K, whether as a result of any new information, future events or otherwise.

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.

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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 the tissue repair programs include the stimulation of new blood vessel formation, modulation of the immune system, 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.

In November of 2023, Longeveron received notice from the World Health Organization ("WHO") that "laromestrocel" has been selected as the proposed International Nonproprietary Name for Longeveron's Lomecel-B™ product. Assuming that there are no third-party objections to that name, the name will be recommended for adoption by the WHO. Longeveron will adopt that name if it is recommended by the WHO.

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 this data shows 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 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 improvement in HLHS survival following the Phase 1 ELPIS I clinical trial has resulted in acceptance by the American Heart Association ("AHA") for a poster presentation at an AHA meeting in November 2023. The ELPIS I trial showed 100 percent survival in children up to 5 years of age after receiving Lomecel-B™, compared to a 20 percent mortality rate observed from historical control data. Based on these findings, the U.S. Food and Drug Administration (the "FDA") granted Lomecel-B™ both Rare Pediatric Disease (RPD") Designation and Orphan Drug Designation ("ODD") for treatment of infants with HLHS. 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 functional and clinical benefit of Lomecel-B™ as part of standard-of-care treatment in HLHS patients.

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1 Sunjay Kaushal, MD, PhD, Joshua M Hare, MD, Jessica R Hoffman, PhD, Riley M Boyd, BA, Kevin N Ramdas, MD, MPH, Nicholas Pietris, MD, Shelby Kutty, MD, PhD, MS, James S Tweddell, MD, S Adil Husain, MD, Shaji C Menon, MBBS, MD, MS, Linda M Lambert, MSN-cFNP, David A Danford, MD, Seth J Kligerman, MD, Narutoshi Hibino, MD, PhD, Laxminarayana Korutla, PhD, Prashanth Vallabhajosyula, MD, MS, Michael J Campbell, MD, Aisha Khan, PhD, Eric Naioti, MSPH, Keyvan Yousefi, PharmD, PhD, Danial Mehranfard, PharmD, MBA, Lisa McClain-Moss, Anthony A Oliva, PhD, Michael E Davis, PhD, 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 Alzheimer's disease 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. Notably, 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 Alzheimer's disease score ("CADS") for both the low-dose Lomecel-B™ group and the pooled treatment groups compared to placebo. Other doses also showed promising results in slowing/prevention of disease worsening. Additionally, a statistically significant improvement versus placebo was observed in the 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"). These findings support both the safety and potential therapeutic benefit of Lomecel-B™ in managing mild Alzheimer's disease, and we believe lays a strong groundwork for subsequent trials in this indication.

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. Our preliminary clinical data suggest that Lomecel-B™ may potentially address these problems through multiple potential mechanisms of action ("MOAs") that simultaneously target key aging-related processes. We are using Lomecel-B™ in registry trials in The Bahamas as part of the real-world data generation for the aging population.

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 magnetic resonance imaging ("MRI") demonstrated whole brain volume loss slowed accompanied by significant preservation of left hippocampal volume 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. We are actively in pursuit of a partnership to propel this initiative forward.

- Limited focus on our international program. In line with the Company's strategic direction for 2024 and moving forward to focus on HLHS and AD as set forth previously, the Company has 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 2024

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

Indication	Geography	Phase 1	Phase 2	Phase 3
HLHS	U.S.			
Aging-related Frailty*	U.S.			
Alzheimer's disease	U.S.			

Figure 1: Lomecel-B™ clinical development pipeline

* Not currently active for 2024

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. 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 converts the normally 4-chamber heart into a 3-chamber one with a single ventricle (the right ventricle) supporting 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 2 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 over 50% enrolled and is funded in part by the NHLBI/NIH. While we cannot predict a specific time when the trial will be fully enrolled, the current plan is that enrollment will be completed in 2024.

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. In addition to the 12-month follow-up evaluation on ELPIS, we continue to follow these patients on an annual basis. As of February 2024, all 10 patients have survived (100%), seven of the patients have reached the age of five and have successfully undergone the third-stage surgery, and two of them have reached the age of six years old, all without the need for a heart transplantation. Based on historical data, over 15% of patients would be expected to have received a heart transplant or have died within three years after the second-stage surgery, rising to nearly 20% by five years. We intended to continue to follow-up with these patients for up to an additional five years, until all patients reach ten years of age.

We are prosecuting a number of patent applications relating to the administration of mesenchymal stem cells for treating HLHS in Canada, Japan, Taiwan, the United States and the Bahamas, with applications having also been ordered for filing in Australia, China, South Korea, and the European Patent Office.

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]. As previously indicated, we are actively in pursuit of a partnership to propel our AD initiative forward.

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 multicenter, 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 multicenter, 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.

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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.*

We are prosecuting or have sent filing instructions for a number of patent applications relating to the administration of MSC for Aging-related Frailty in Australia, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, Singapore, South Korea, New Zealand, Taiwan, the Bahamas and 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.

Our lead product, Lomecel-B™, consists of human allogeneic bone-marrow derived MSCs 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 bone marrow supply contracts in place with two suppliers: the Oklahoma Blood Institute and All Cells, with a potential third vendor in process. These suppliers provide adequate bone marrow for our current and anticipated needs; however, if one or both 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 product to be a novel therapeutic 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.

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 1,550 worldwide as of January 2024.

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

Name	Corporate Headquarters	Clinical stage pipeline indication(s)
Athersys, Inc.	U.S.	Ischemic stroke; ARDS; GvHD; Acute Myocardial Infarction
BioCardia, Inc.	U.S.	Heart failure; Acute myocardial infarction
BrainStorm Cell Therapeutics	U.S.	ALS; MS
Lisata Therapeutics	U.S.	Coronary microvascular dysfunction; Critical limb ischemia; Diabetic kidney disease
CorestemChemon	South Korea	ALS (Commercial in South Korea); Lupus
Cynata Therapeutics	Australia	GvHD
Healios K.K.	Japan	Ischemic stroke; ARDS
Medipost	South Korea	Osteoarthritis (commercial); BPD; AD
Mesoblast Ltd.	Australia	Heart failure, low back pain, GvHD; ARDS; Crohn's Disease, HLHS
Pluri, Inc.	Israel	CLI; ARDS; ARS; GvHD
ReNeuron	U.K.	Ischemic stroke; Retinitis pigmentosa
SanBio Co., Ltd.	Japan	Ischemic stroke; Traumatic brain injury
Stemedica Cell Technologies	U.S.	Ischemic stroke; heart failure; AD

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.

Aging Frailty Competitive Intelligence Research

Per ClinicalTrials.gov, as of February 18, 2024, there were 107 clinical trials in Aging Frailty listed on the site including all stages (ongoing, completed, terminated, withdrawn) and all interventions. Of the 107 listed studies, there were 29 studies listed which are currently enrolling patients with aging frailty. Among those, allogeneic bone-marrow-derived mesenchymal stem cell were listed as an intervention in three studies:

- "A Study to Evaluate Allogenic Bone-Marrow Mesenchymal Stromal Cell Product StromaForte in Aging Frailty Patients", sponsored by Cellcolabs Clinical SPV Limited. This phase I/IIa study in frail patients is designed to assess the safety of intravenous human allogenic bone marrow-derived mesenchymal stromal cell product StromaForte by reporting the number of adverse events assessed by Common Terminology Criteria. 12 male and female patients aged 60 to 85 years will be enrolled. The study initiated on October 2, 2023, with estimated completion date November 28, 2024. The study is currently enrolling patients in United Arab Emirates.

- "Safety of Cultured Allogeneic Adult Umbilical Cord Derived Mesenchymal Stem Cell Intravenous Infusion for Aging Frailty", sponsored by The Foundation for Orthopedics and Regenerative Medicine. This trial will study the safety and efficacy of intravenous infusion of cultured allogeneic adult umbilical cord derived mesenchymal stem cells for the treatment of Aging Frailty. The plan is to enroll 20 patients. The study initiated on August 24, 2021 and estimated completion study date is December 1, 2027.

- "A Study of Human Allogeneic Bone-marrow-derived Mesenchymal Stromal Cell Product (StromaForte) in Patients With Aging Frailty", sponsored by Cellcolabs Clinical LTD. The goal of this phase I/II clinical trial is to evaluate the safety and tolerability of intravenous infusion of human allogeneic bone-marrow-derived mesenchymal stromal cell product StromaForte in patients with aging frailty. The main questions it aims to answer are: 1) To assess the safety and tolerability after 28 days of injection by reporting the number of adverse events assessed by Common Terminology Criteria For Adverse Events ("CTCAE") 2) Observe the change in inflammatory markers from baseline to six months (baseline to 28, 84, and 168 days post-infusion.). The study was initiated on October 9, 2023 and the estimated date of completion is January 10, 2025.

Alzheimer's Disease Competitive Intelligence Research

Per ClinicalTrials.gov, as of February 18, 2024, there were 3,334 studies listed on the site studying Alzheimer's disease, including all stages (ongoing, completed, terminated, withdrawn) and all interventions. Among those, 401 studies were listed with Alzheimer's disease as an indication and stem cells as an intervention. Seventeen of them were listed to conduct clinical studies with mesenchymal stem cells in all stages and only one of them is currently enrolling patients on the study:

- "Allogeneic Human Mesenchymal Stem Cells for Alzheimer's Disease", Phase 2 study, sponsored by Stemedica Cell Technologies, Inc. The main goals of this study are 1) To assess the safety and tolerability of ischemia-tolerant allogeneic human mesenchymal stem cells ("hMSCs") manufactured by Stemedica versus placebo administered intravenously to subjects with mild to moderate dementia due to Alzheimer's disease and 2) To assess the preliminary efficacy of hMSCs versus placebo in subjects with Alzheimer's-related dementia, as evidenced by neurologic, functional, and psychiatric endpoints. This study planned to enroll 40 patients in United States, California. The study was initiated on June 1, 2016, and the estimated study completion date is December 31, 2024.

There are many other pharmaceutical and biotechnology companies that are conducting clinical trials of various therapeutics for the treatment of AD.

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.

By letter dated November 20, 2023, Longeveron was informed by the WHO that "laromestrocel" has been selected as the proposed International Nonproprietary Name for Longeveron's Lomecel-B™ product. Assuming that there are no third-party objections to that name, the name will be recommended for adoption by the WHO. Longeveron will adopt that name if it is recommended by the WHO.

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 MSCs 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™ MSCs are approved by the FDA, third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. Our ability to deter and, if necessary, to stop third parties from making, using, selling, offering to sell or importing our 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, or 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 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 MSCs in a subject that exhibits "inflammaging." In this family we own and are continuing to prosecute and maintain one allowed U.S. patent application, one allowed application and one pending application in Japan, one pending application in Australia, and one pending application in the European Patent Office. Another European Patent Office application has been allowed, and pending conclusion of the opposition period is planned to be 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 received a notice of allowance for our U.S. patent application, and 14 patent applications outside of the U.S. (in 12 jurisdictions). The Chinese counterpart of the application has been allowed. Patents have issued in Japan and Taiwan, and a patent registration has issued 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. In addition to the applications in Taiwan and The Bahamas, PCT national or regional phase applications were filed in the U.S., Australia, Canada, China, the European Patent Organization, Israel, Japan, South Korea, New Zealand, Singapore, South Africa, and Hong Kong. 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 won and are continuing to maintain a patent registration in the Bahamas. The U.S., Japanese, and European properties are a national or regional phase applications based on a PCT application filed on June 15, 2018 and claiming priority to a U.S. provisional application filed in June 2017. The registration in the Bahamas claims priority to that same provisional application but was not filed using the PCT. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in June 2038. Longeveron has elected to take no further action and to allow to become abandoned, properties in the family in Australia, Canada, China, Hong Kong, Israel, Korea, Singapore, South Africa, South Korea, Taiwan, and New Zealand.

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

Use of Mesenchymal Stem Cells in Treatment of Juvenile Hypoplastic Left Heart Syndrome. This patent family is directed to treatment of HLHS with allogeneic MSCs. In this family we own pending applications in Taiwan, the Bahamas, and the PCT. These applications share a common priority date of July 2021. National and regional phase applications based on pending PCT application, have been filed or are expected to be filed in Australia, Canada, China, the European Patent Office, Japan, South Korea, Taiwan, and the United States. 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 MSCs 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 or are expected to be 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 MSCs to treat AD. We own pending patent applications in Australia, the Bahamas, South Korea, Singapore, South Africa, Israel, Canada, Hong Kong, New Zealand, China, Japan, the European Patent Office, and the United States. Those applications claim priority to three separate U.S. provisional applications, the earliest of which was filed in September 2020. If issued, and assuming that all maintenance and annuity fees are paid, patents arising from these applications are expected to expire in September 2041.

License Agreements and Strategic Collaborations

The University of Miami ("UM")

On November 20, 2014, we entered into an Exclusive License Agreement with UM (the "UM License") for the use of certain Aging-related frailty-related MSC technology rights developed by our Chief Science Officer, Dr. Joshua Hare, at UM. The UM License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how specifically related to the development of the culture-expanded MSCs for aging-related frailty used at the Interdisciplinary Stem Cell Institute of UM ("IMSCs"), all standard operating procedures used to create the 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 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 HLHS IND with ckit+ cells; and (b) UMP-438 titled "Method of Determining Responsiveness to Cell Therapy in Dilated Cardiomyopathy."

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, 2023, we had accrued $50,000 in milestone fees payable to UM.

CD271

On December 22, 2016, we entered into a worldwide exclusive license agreement with JMH MD Holdings ("JMHMD"), an affiliate 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 $25,000 for each of the years ended December 31, 2023 and 2022, 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.

Trademarks

We have registered trademarks or applied for registered trademarks for "Longeveron" in the following jurisdictions. We have begun to phase 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"	"LMSC"
The Bahamas		Registered	Closed
Brazil		Registered	
Canada		Registered	
China		Registered	Registered
European Union		Registered	
Hong Kong		Registered	
India		Registered	
Japan		Registered	Registered
South Korea		Registered	
Morocco		Registered	Registered
Panama		Registered	
Switzerland		Registered	
Taiwan		Registered	
U.S.	Allowed	Allowed	Registered
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.

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 access to certain data 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:

- 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. 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 filing of a priority BLA. 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. 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, or 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 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.

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 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. Receiving a fast-track designation is not the same as receiving FDA product approval.

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. 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. 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 adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch 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.

In addition to the potential award of a seven-year ODE 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 are also exempt from program fees otherwise required under the PDUFA. For fiscal year 2024, the application fee for a new drug or biologic requiring clinical studies is $4,048,695, and the program fee for approval of prescription drugs and biologics is $416,734.

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 agencies 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.

Other Healthcare Laws

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, False Claims Act, Consumer Fraud Act, 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, 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.

Japanese Laws and Regulations

There are two primary Acts in Japan that regulate regenerative medicine development and offer two pathways to market for regenerative medicine therapeutic candidates: The Act pm the Safety of Regenerative Medicine ("ASRM") and the Pharmaceuticals and Medical Devices Act ("PMDA").

The ASRM allows physicians to provide cellular therapies to patients through an application process that is regulated by the Japanese Ministry of Health, Labor and Welfare ("MHLW"). Manufacturers of cell and gene therapy products wishing to utilize this pathway must identify and work with a partner clinic or hospital which enables the clinic to act as the distributor, with the manufacturer receiving a fee or a royalty, for example.

The PMDA includes special treatment for regenerative medicine products and identifies them as a stand-alone medical category with a novel "conditional approval" system. Sponsors seeking manufacturing approval need to provide clinical data to show that the product does not have any major safety concerns, clinical data to demonstrate "probable" efficacy, and satisfy established chemistry, manufacturing and controls criteria.

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, 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.

Human Capital Management

As of December 31, 2023, we had 23 full-time employees, one part-time employee and one full-time consultant. Among those, four had M.D. or Ph.D. degrees, two are Certified Public Accountants, and one has a J.D. degree. Of these full-time employees and consultants, 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.

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

Available Information

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

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are filed with the Securities and Exchange Commission ("SEC"). We are subject to the informational requirements of the Exchange Act, and we file or furnish reports, proxy statements and other information with the SEC. Such reports and other information we file with the SEC are available free of charge at our website *www.longeveron.com* when such reports are available on the SEC's website. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at *www.sec.gov*. Longeveron periodically provides other information for investors on our corporate website, including press releases and other information about financial performance, information on corporate governance and presentations. Our website address is *www.longeveron.com*, and we make our filings with the SEC available on the Investor Relations page of our website. Our references to website URLs are intended to be inactive textual references only. The information found on, or that can be accessed from or that is hyperlinked to, our website does not constitute part of, and is not incorporated into, this Form 10-K. Our Class A common stock is traded on the Nasdaq 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 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 may not be able to raise additional capital necessary to continue as a going concern;

- We have a history of losses and may not be able to achieve profitability going forward;
- There are no FDA-approved allogenic, 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, and
- 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.

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 therapeutic 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 therapeutic 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.
- We could lose our listing on the Nasdaq Capital Market if our current share price continues to decrease. The loss of our Nasdaq listing would in all likelihood make our Class A common stock significantly less liquid and adversely affect its value.
- 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.

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 22 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 Lomecel-B™. 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 MSCs, any negative developments regarding the therapeutic potential or side effects of our MSCs, or regarding scientific and medical knowledge about MSCs in general, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We are subject to the risks of failure inherent in the development of 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 not autologous (i.e., taken from, and given to, the same individual) but are instead allogeneic (i.e., taken from one individual and given to a different person) 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 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 our other indications. 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 in these indications. 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 these indications.

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 there will be consensus regarding the definition of the condition or 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 these indications may be difficult to determine. To the extent the Company decides to pursue these indications, 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 can 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, 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 to meet future commercial demand at an acceptable cost. In addition, the expansion of MSCs through our proprietary manufacturing methods utilizes biologic growth media that may be in limited supply. Our 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 product demand could limit our potential revenues.

MSCs 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, but the public may not be able to, or may fail to, differentiate our use of adult MSCs from the use of embryonic stem cells or fetal tissue by others, which could result in a negative perception of our company or our future products or product candidates, thereby reducing demand, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may obtain MSCs from volunteer adult bone marrow donors from non-profit organizations that collect and process tissue donations. Bone marrow donors receive payment, but ethical concerns have been raised by some about the use of donated human tissue in a for-profit setting, as we are doing. Future adverse events in the field of stem cell therapy, changes in public policy, or changes to the FDA's regulatory approval framework for these products could also result in greater governmental regulation of our 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 our approved product. 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, 2023, we had $5.4 million in cash and cash equivalents and marketable securities. 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 and outbreaks.

The global outbreak of COVID-19 continues to impact countries, communities, supply chains and markets. The COVID-19 pandemic has impacted and continues to impact 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. The COVID-19 pandemic and other public health risks could also disrupt the production capabilities of our contract manufacturing facility. Further, the outbreak of COVID-19 has heightened the risk that a significant portion of our workforce will suffer illness or otherwise be unable to work. The impact of the COVID-19 pandemic is fluid and continues to evolve, and therefore, we cannot currently predict the extent to which our business, clinical trials, results of operations, financial condition or liquidity will ultimately be impacted. In addition, COVID-19 or 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 cGCP, 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 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 withdrawal of the United Kingdom from the European Union, and 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 may not be able to raise additional capital necessary to continue as a going concern.

As of December 31, 2023, we had cash and cash equivalents of $4.9 million and marketable securities of $0.4 million. We have prepared a cash flow forecast which indicates that we will have sufficient cash to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. As a result, we will need to raise additional capital to continue as a going concern. 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, 2023, with respect to this uncertainty. Our ability to continue as a going concern is dependent on our available cash, how well we manage that cash, and our operating requirements. If we are unable to raise additional capital when needed, we would be forced to delay, reduce or eliminate our clinical trial programs, commercialization efforts and other business activities.

We have a history of losses and may not be able to achieve profitability going forward.

We have experienced significant losses since inception and, at December 31, 2023 and 2022, had an accumulated deficit of approximately $85.0 million and $62.8 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. In such event, we will not have sufficient cash flow to meet our obligations or make progress in our clinical programs and will need to raise additional capital.

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 80 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.

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.

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

Our patent applications on MSC technology, in particular, include claims directed to therapeutic uses and kits comprising MSCs. Patents with such claims tend to be more vulnerable to challenge by other parties than patents with extremely narrow claims. Also, our pending patent applications may not issue, may issue with substantially narrower claims than currently pending claims, or we may not receive any additional patents. Further, the laws of

foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. Our patents might not contain claims that are sufficiently broad to prevent others from practicing our technologies or from competing with us with their own technology in the fields of interest to us.

Although the Company has obligations of assignment and has been assigned patents and patent applications concerning stem cell products and their uses, none of those patents or presently pending applications has granted claims or pending claims that, if granted, would 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, requires 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 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™ MSCs are approved by the FDA, third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. We may not be able to prove in litigation that any patent enforced against us is invalid.

Additionally, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our 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 office's 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, of 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 therapeutic 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 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 product candidates 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 agencies 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 commitments. Failure to comply with or meet those requirements or commitments could result in withdrawal of the approved application by FDA. Regulatory agencies 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 agencies 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 signaling cell 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 MSCs 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 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, cGCP and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- 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;
- FDA does 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; 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 have only been two FDA-approved treatments. Aduhelm® (aducanumab-avwa), an amyloid beta-directed antibody, was approved by FDA in 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 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.

Producing and marketing an approved drug or other medical product is subject to significant and costly post-approval regulation.

Even if approved for commercial sale, we may be required to conduct Phase 4 (i.e., post-marketing) clinical trials or comply with other post-marketing requirements or commitments for the products. Even if we obtain approval of a product, we can only market the product for the approved indications. After granting marketing approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers, and manufacturing facilities, creating 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 withdrawal of product approval. Further, regulatory agencies may establish different or additional regulations that could impact the post-marketing status of our products.

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 therapeutic 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 REMS program in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, 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 cGMP and Good Clinical Practice ("GCP"), 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 cGMP 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. The FDA may also require a REMS as a condition of approval of our therapeutic candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our therapeutic candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

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, warning 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 therapeutic candidates; and
- consent decrees or injunctions or the imposition of civil or criminal penalties.

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. 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, 2020, 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 therapeutic 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 former 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 former 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 former 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, former 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, former 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, former 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, 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.

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 therapeutic candidates for which we may obtain regulatory approval or the frequency with which any such therapeutic candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved therapeutic 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.

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 Current Good Tissue Practice ("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 such components 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 therapeutic 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 by third-parties with 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 GCP requirements, for therapeutic candidates in clinical development. Regulatory authorities enforce GCP 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 GCP 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 GCP 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 or absenteeism due to the COVID-19 pandemic, 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 therapeutic candidates. As a result, our financial results and the commercial prospects for our therapeutic 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 regulators 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 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 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 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 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 may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental 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. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union 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 European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union 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 European Union, 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 European Union, 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 agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the 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 has been 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 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 agencies 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 agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, an approved product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label, 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 those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

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 upon approval for this indication. This voucher program has been extended, but there is no guarantee the Congress will extend it again in the future. If we do receive a priority review voucher 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. 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.

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.

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 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 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. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- 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;

- 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
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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. Some 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, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union 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 may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental 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, accept payments 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 regenerative medicines 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 agencies, 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 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 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 be regenerative medicines that will 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. Recently the Securities and Exchange Commission (SEC) and Department of Justice (DOJ) have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. 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. 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 therapeutic 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 beginning of the second quarter of 2024. 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 candidate. 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 candidate 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 therapeutic 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 only for various amounts of time in 2024 depending on the amount of net proceeds we obtain. 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 therapeutic candidates;
- the potential additional expenses attributable to adjusting our development plans (including any supply-related matters) to the COVID-19 pandemic;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future therapeutic 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 therapeutic 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 therapeutic 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 therapeutic 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 therapeutic 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 therapeutic 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.

We could lose our listing on the Nasdaq Capital Market if our current share price continues to decrease. 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 23, 2024 our Class A common stock closing bid price was $0.518. In the event that our closing bid price falls below $1.00 per share (the "Minimum Bid Price Requirement") for more than thirty (30) days, as required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), we could receive a notification letter from the Nasdaq Listing Qualifications Department, commencing delisting proceedings. The receipt of a Nasdaq letter does not result in the immediate delisting of the Company's Class A common stock from the Nasdaq Capital Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (the "Compliance Period Rule"), a company is provided an initial period of 180 calendar days (the "Compliance Date") to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180-day period, the bid price closes at $1.00 or more per share for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, the Staff would provide written notification to the Company that it again complies with the Minimum Bid Price Requirement and the Class A common stock will continue to be eligible for listing on The Nasdaq Capital Market unless other eligibility deficiencies exist.

If the Company were to not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company would be required to meet the continued listing requirement for the market value of publicly held shares and all other

initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of its intention to cure the deficiency during the additional compliance period.

If it appears to the Staff that the Company would not be able to cure the deficiency, the Staff will provide written notice to the Company that its Class A common stock will be subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Hearing Panel (the "Panel"). The Company expects that its Class A common stock would remain listed pending the Panel's decision, subject to the Company's ability to regain compliance with the Stockholders' Equity Requirement (as defined below). There can be no assurance that, if the Company does appeal the Staff's delisting determination to the Panel, such appeal would be successful.

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 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 control the direction of our business and their ownership of our common stock can prevent other stockholders from influencing significant decisions.

As of February 16, 2024, two holders of our Class B common stock, Joshua M. Hare, co-founder, Chief Science Officer and Chairman of the Board of Directors, and Donald M. Soffer, co-founder and former member of our Board of Directors, control voting rights over approximately 84% of the combined voting power of our Class A common stock and Class B common stock. For so long as holders of Class B common stock continue to hold their shares, they will be able to significantly influence or effectively control the composition of our Board of Directors and the approval of actions requiring stockholder approval through their voting power. Accordingly, for such period of time, these holders will have significant influence with respect to our management, business plans and policies. 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.

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 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 common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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 16, 2024, we had an aggregate of 84,295,000 shares of Class A common stock authorized and of that approximately 63,597,015 not issued, outstanding or reserved for issuance (for purposes of warrant exercise or under the Company's current 2021 Equity Incentive 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 a product candidate, 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, which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates 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 agencies' 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, 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 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 will be 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., including specifically in Japan, 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 therapeutic 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 therapeutic 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 website. In addition, we may encounter attacks on social media regarding our company, management, therapeutic candidates or 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 Vice President, Business Operations ("VPBO"), other members of management and relevant management committees, including Company's Senior Leadership Team ("SLT"). The Company, as part of cost-cutting initiatives in 2024, has eliminated the VBPO position; the obligations of that position as it relates to cybersecurity oversight and risk management will be undertaken by the Company's General Counsel.

- **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 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, 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 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 VPBO who shares data with the SLT, Audit Committee and the Board, 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 VPBO, in coordination with the SLT, oversees the Company's ERM process, including the management of risks arising from cybersecurity threats. The VPBO 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 VPBO, Chief Financial Officer ("CFO"), and General Counsel.

The VPBO, 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 throughout the Company are deployed 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 VPBO for align business and technical strategies, decisions, and implementations. The VPBO has over 35 years 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 office is 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. 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.

On September 13, 2021, the Company and certain of our 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 alleged 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 complaint sought unspecified damages on behalf of a proposed class of purchasers of our

Class A common stock during said period. On July 12, 2022, all parties preliminarily agreed to settle the action for approximately $1.4 million, which amount was accrued as of June 30, 2022, and was paid during the quarter ended June 30, 2023.

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, 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.

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."

Holders of Common Stock

As of February 16, 2024, there were 15 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, 10,294,603 shares of our Class A common stock and 14,839,993 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 Purchased (a)	Average Price Paid per Share (or Unit)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 – 31, 2023	8,809	$ 2.29	—	—
November 1 – 30, 2023	—	$ —	—	—
December 1 – 31, 2023	361	$ 2.20	—	—
Total	9,170	$ 2.29	—	—

(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.

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 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, 2023 the Company had an accumulated deficit of $85.0 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 second quarter of 2024. 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. 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.

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 reconstructive surgeries, typically at 10 days, 4 months, and approximately 4 years of life. 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 16, 2024, 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 6,798,041 shares of Common Stock through our IPO, a December 2021 private issuance of public equity ("PIPE") offering (the "2021 PIPE Offering"), a September 2023 rights offering, an October 2023 registered direct offering with pre-funded warrants and concurrent private placement (the "October 2023 Offering") and a December 2023 registered direct offering and concurrent private placement (the "December 2023 Offering"), along with warrants to purchase (i) 106,400 shares of common stock at an initial exercise price of $12.00 per share issued to the underwriter in our IPO in February 2021 (the "IPO Warrants"), (ii) 1,169,288 shares of Common Stock at an initial exercise price of $17.50 per share in the 2021 PIPE Offering (the "PIPE Purchaser Warrants") as well as representative warrants to purchase 46,722 shares of common stock at an exercise price of $17.50 per share (the "PIPE Representative Warrants" and together with the PIPE Purchaser Warrants the "PIPE Warrants"), (iii) 4,848,486 warrants to purchase shares of common stock at an exercise price of $1.65 per share (the "October 2023 Private Placement Warrants") as well as placement agent warrants to purchase 169,697 shares of common stock at an exercise price of $2.0625 per share (the "October 2023 Placement Agent Warrants") in the October 2023 Offering (collectively, the "October 2023 Warrants"), and (iv) 1,355,301 warrants to purchase shares of common stock at an exercise price of $1.62 per share (the "December 2023 Private Placement Warrants") as well as placement agent warrants to purchase 94,871 shares of common stock at an exercise price of $2.1813 per share (the "December 2023 Placement Agent Warrants") in the December 2023 Offering (collectively, the "December 2023 Warrants"). The exercise price of the PIPE Purchaser Warrants were re-set in accordance with their terms upon announcement and in connection with the consummation of the September 2023 rights offering to $5.25 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.

Components of Our Results of Operations

Revenue

We have generated revenue from three sources:

- 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.
- 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.

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.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of royalty and license fees associated with our agreements with the University of Miami, investor and public relations costs, as well as attending and sponsoring industry, investment, organization and medical conferences and events.

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: first, those activities that should be identified as research and development; second, the elements of costs that should be identified with research and development activities, and the accounting for these costs; and third 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, share-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

General and administrative expenses consist primarily of salaries and other related costs, including stock-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.

We expect that our general and administrative expenses will continue to be significant in the future as we increase our headcount to support increased administrative activities as a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other Income and Expenses

Interest income consists of interest earned on cash equivalents and marketable securities. We expect our interest income to fluctuate due to changes in the current cash and marketable securities balances. Other income consists of funds earned that are not part of our normal operations. In past years they have been primarily a result of tax refunds received for social security taxes as part of a research and development tax credit program.

Income Taxes

No provision for income taxes has been recorded for the years ended December 31, 2023, and 2022. 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, 2023 AND 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022, together with the changes in those items in dollars (in thousands):

	Year Ended December 31,		Increase (Decrease)
	2023	2022	
Revenues	$ 709	$ 1,222	$ (513)
Cost of revenues	488	725	(237)
Gross profit	221	497	(276)
Operating Expenses			
General and administrative	11,401	8,119	3,282
Research and development	9,066	9,370	(304)
Selling and marketing	783	1,051	(268)
Total operating expenses	21,250	18,540	2,710
Loss from operations	(21,029)	(18,043)	(2,986)
Other (expense) and income			
Lawsuit expense	(30)	(1,398)	1,368
Other tax credits	23	306	(283)
Other (expense) income, net	(377)	300	(677)
Total other expenses, net	(384)	(792)	408
Net loss	$ (21,413)	$ (18,835)	$ (2,578)

Revenues, Cost of Revenues and Gross Profit: Revenues for the years ended December 31, 2023 and 2022 were $0.7 million and $1.2 million, respectively. 2023 revenues decreased $0.5 million, or 42%, when compared to 2022 as a result of decreased grant and lower participant demand for our Bahamas Registry Trial. Grant revenue for the years ended December 31, 2023 and 2022 was less than $0.1 million and $0.3 million, respectively. The decrease of $0.2 million, or 85%, when compared to 2022, was primarily due to a reduction in grant funds available due in part to the completion of the grant-funded clinical trials. Clinical trial revenue, which is derived from the Bahamas Registry Trial, for the years ended December 31, 2023 and 2022 was $0.7 million and $0.9 million, respectively. Clinical trial revenue for the year ended December 31, 2023 decreased by $0.2 million, or 29%, when compared to 2022 as a result of decreased participant demand.

Related cost of revenues was $0.5 million and $0.7 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $0.2 million, or 33%, was primarily due to the decrease in the revenues earned from the Bahamas Registry Trials and reduced direct costs associated with our grants program. This resulted in a gross profit of approximately $0.2 million for the year ended December 31, 2023, a decrease of $0.3 million, or 56%, when compared with a gross profit of $0.5 million for 2022.

General and Administrative Expense: General and administrative expenses for the year ended December 31, 2023 increased to approximately $11.4 million, compared to $8.1 million for the same period in 2022 . The increase of approximately $3.3 million, or 40%, was primarily related to an increase of $1.6 million for compensation and benefit expenses (including $0.4 million of separation costs), $1.0 million in legal, professional and consulting fees, $0.4 million of public company expenses, $0.2 million in equity-based compensation costs allocated to general and administrative expenses, and $0.1 million for higher board fees.

Research and Development Expenses: Research and development expenses for the year ended December 31, 2023 decreased to approximately $9.1 million, from approximately $9.4 million for the same period in 2022. The decrease of $0.3 million, or 3%, was primarily due to decreases of $0.5 million in equity-based compensation allocated to research and development expenses and $0.3 million in compensation and benefits, offset by increases of $0.4 million in supplies and costs to manufacture Lomecel-B™ and $0.2 million in research and development expenses that were not reimbursable by grants. Research and development expenses consisted primarily of the following items (less those expenses allocated to the cost of revenues for the grants)(in thousands):

	Year Ended December 31,	
	2023	2022
Clinical trial expenses-statistics, monitoring, labs, sites, etc.	$ 4,349	$ 4,170
Supplies and costs to manufacture Lomecel-B™	1,214	817
Employee compensation and benefits	1,861	2,203
Equity-based compensation	555	1,096
Depreciation	722	681
Amortization	224	212
Travel	38	72
Other activities	103	119
Total	$ 9,066	$ 9,370

Selling and Marketing Expenses: Selling and marketing expenses for the years ended December 31, 2023 and 2022 were $0.8 million and $1.1 million, respectively. The decrease of $0.3 million, or 25%, was primarily due to decreases in investor relations and international development expenses.

Non-operating Lawsuit expense: Non-operating Lawsuit expense for the years ended December 31, 2023 and 2022 was less than $0.1 million and approximately $1.4 million, respectively. Additional detail can be found in Part I, Item 3 “Legal Proceedings” of this Form 10-K. Legal expenses incurred in ordinary business activities are reported within general and administrative expenses.

Other tax credits: Other tax credits for each of the years ended December 31, 2023 and 2022 was less than $0.1 million and $0.3 million, respectively. Other tax credits was greater in 2022 due to receiving the Employee Retention Credit under the CARES Act which encourages businesses to keep employees on their payroll. Eligible businesses receive a refundable tax credit of up to 50% of up to $10,000 in wages paid.

Other (Expense) Income, net: Other expense for the years ended December 31, 2023 and 2022 was $0.4 million and $0.8 million, respectively. Other expense for 2023 decreased mainly as a result of non-operating lawsuit expenses of $1.4 million in 2022, compared to less than $0.1 million in 2023. This decrease was partially offset 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. Also recorded in other (expense) income in 2022 was approximately $27,000 for a gain resulting from foreign currency changes and $27,000 of sublease rental income.

Net Loss: Net loss increased to approximately $21.4 million for the year ended December 31, 2023, from a net loss of $18.8 million for the same period in 2022. The increase in the net loss of $2.6 million, or 14%, 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,	
	2023	2022
Net cash used in operating activities	$ (19,002)	$ (13,969)
Net cash proved by (used in) investing activities	8,186	(677)
Net cash provided by (used in) financing activities	5,262	(509)
Net decrease in cash and cash equivalents	$ (5,554)	$ (15,155)

Operating Activities. We have incurred losses since inception. 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. Net cash used in operating activities for the year ended December 31, 2022 was $14.0 million, consisting primarily of our net loss of $18.8 million, partially offset by $1.4 million in non-operating lawsuit expenses not paid until May 2023 and other non-cash expenses of $2.2 million in equity-based compensation expenses and $0.9 million in depreciation and amortization expenses.

Investing Activities. Net cash provided by investing activities for the 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. Net cash used in investing activities for year ended December 31, 2022 was $0.7 million, consisting primarily of an increase in purchases of equipment of $0.6 million and purchases of intangibles of $0.3 million.

Financing Activities. 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. Net cash used in financing activities for the year ended December 31, 2022 was $0.5 million consisting primarily of $0.5 million in payment of taxes and consultants.

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 $83.9 million in gross proceeds from the issuance of equity. As of December 31, 2023, the Company had cash and cash equivalents of $4.9 million, marketable securities of $0.4 million and working capital of approximately $2.0 million.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. 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 are actively seeking financing opportunities to extend our cash runaway while taking measures to reduce our cash expenditures as we focus our resources on our primary strategic program in HLHS. These cost saving measures include the discontinuation of our Aging-related Frailty clinical trial in Japan, related staff reductions, and continued prudent management of discretionary spend.

Capital Raising Efforts

In our IPO, we sold 2,910,000 shares of Class A common stock at a public offering price of $10.00 per share for aggregate gross proceeds of $29.1 million, inclusive of the underwriter's partial exercise of its over-allotment option, prior to deducting underwriting discounts, commissions, and other offering expenses.

The underwriter received warrants to purchase 106,400 Class A common stock shares. 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 $12.00 per Class A common stock share. During 2021, the underwriters assigned 95,760 of the warrants to its employees. As of December 31, 2023, 51,061 warrants have been exercised, which provided net proceeds to the Company of $0.6 million.

On December 3, 2021, we closed our 2021 PIPE Offering, whereby we undertook a private purchase and sale to certain accredited investors of an aggregate of 1,169,288 shares of our Class A common stock and Purchase Warrants to purchase 1,169,288 shares of Class A common stock at an initial exercise price of $17.50 per share, resulting in aggregate gross proceeds of $20.5 million prior to deducting fees and offering expenses. We also issued Representative Warrants exercisable for 46,772 shares of Class A common stock to affiliates of Placement Agent with an initial exercise price of $17.50 per share.

On August 16, 2023, the Company announced its rights offering, which triggered the downward pricing mechanism on certain warrants of the 2021 PIPE Offering, at which time these warrants were adjusted downward to an exercise price of $5.25 for the period remaining through expiration.

On June 27, 2023, the Company filed a registration statement with the SEC to conduct a tradeable subscription rights offering for up to $30.0 million of shares of Class A common stock to its stockholders and holders of certain warrants to purchase common stock On July 28, 2023, the Company filed a first amendment to the registration statement. On August 16, 2023, the registration statement was declared effective by the SEC, and on August 22, 2023, the Company launched the subscription rights offering at a subscription price of $3.00 per share of Class A common stock. On September 21, 2023, the subscription period for the rights offering of the Company expired. At the end of the subscription period, the Company sold 108,497 shares of its Class A common stock at a price of $3.00 per share. There were no net proceeds to the Company after deducting the $0.3 million of expenses associated with the rights offering.

On October 11, 2023 the Company entered into a securities purchase agreement with an institutional and accredited investor (the "Purchaser") relating to the registered direct offering and sale of an aggregate of 2,365,000 shares of the Company's Class A common stock, par value $0.001 per share and pre-funded warrants to purchase up to 59,243 shares of Class A common stock at an exercise price of $0.001 per share, at a purchase price of $1.65 per share of common stock and $1.649 per pre-funded Warrant (the "October 2023 Registered Direct Offering"), which Offering closed and was funded on October 13, 2023.

In a concurrent private placement with the October 2023 Registered Direct Offering, the Company also sold to the Purchaser unregistered Series A warrants to purchase up to an aggregate of 2,424,243 shares of its Class A common stock and unregistered Series B warrants to purchase up to an aggregate of 2,424,243 shares of its Class A common stock (the "October 2023 Private Placement" and together with the October 2023 Registered Direct Offering, the "October 2023 Offering"). The unregistered Series A warrants have an exercise price of $1.65 per share, became

exercisable on December 26, 2023, following receipt of stockholder approval of the issuance of the shares issuable upon exercise of the Series A warrants, and have a term of five and one-half years from the date of issuance. The unregistered Series B warrants have an exercise price of $1.65 per share, became exercisable the same times as the Series A warrants, and have a term of eighteen months from the date of issuance. Each warrant is exercisable for one share of Class A common stock. The net proceeds to the Company from the Offering and Private Placement was approximately $3.4 million, after deducting placement agent fees and other offering expenses paid by the Company.

On December 20, 2023 the Company entered into a securities purchase agreement with an institutional and accredited investor (the "Purchaser") relating to the registered direct offering and sale of an aggregate of 1,355,301 shares of the Company's Class A common stock, par value $0.001 per share, at a purchase price of $1.745 per share of common stock (the "December 2023 Registered Direct Offering"), which Offering closed and was funded on December 22, 2023.

In a concurrent private placement on December 22, 2023, the Company also sold to the Purchaser unregistered long-term warrants to purchase up to an aggregate of 1,355,301 shares of its Class A common stock (the "December 2023 Private Placement", and together with the December 2023 Registered Direct Offering, the "December 2023 Offering"). The unregistered December 2023 Private Placement warrants have an exercise price of $1.62 per share, became immediately exercisable upon issuance, and expire on June 20, 2029, and have a term of five and one-half years from the date of issuance. The net proceeds to the Company from the 2023 December 2023 Offering was approximately $2.0 million, after deducting placement agent fees and other offering expenses paid by the Company.

Grant Awards

From inception through December 31, 2023, 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, 2023, and 2022, the amount of unused grant funds that were available for us to draw was approximately $0.1 million and $0.8 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, MD, PhD, 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 believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. 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 are actively seeking financing opportunities to extend our cash runaway while taking measures to reduce our cash expenditures as we focus our resources on our primary strategic program in HLHS. These cost saving measures include the discontinuation of our Aging-related Frailty clinical trial in Japan, related staff reductions, and continued prudent management of discretionary spend.

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, 2023, we have $2.0 million in operating lease obligations and $1.5 million in 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.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition, results of operations and liquidity are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP"). The preparation of our financial statements and related disclosures requires us to make estimates, judgements and assumptions that affect the reported amounts of assets and liabilities and the 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. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may materially differ from these estimates under different assumptions or conditions. On an on-going basis, we review our estimates to ensure that they appropriately reflect changes in our business or new information as it becomes available.

While our significant accounting policies are described in more detail in the notes to our financial statements included in this 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.

Impairment of Long-Lived Assets. We evaluate 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. Management determined that there was no impairment of long-lived assets during the years ended December 31, 2023 and 2022.

Revenue recognition. Effective January 1, 2018, we adopted ASC Topic 606, Revenue from Contracts with Customers, which establishes a single and comprehensive framework on how much revenue is to be recognized, and when. The core principle is that a vendor should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the vendor expects to be entitled in exchange for those goods or services. Revenue will be recognized by a vendor when control over the goods or services is transferred to the customer.

We recognize revenue when performance obligations related to respective revenue streams are met. For grant revenue, we consider the performance obligation met when the grant related expenses are incurred or supplies and materials are received. For clinical trial revenue, we consider the performance obligation met when the participant has received the therapy. For Contract Manufacturing Revenue, we consider the performance obligation met when the contractual obligation and/or statement of work has been satisfied.

Research and development expense. Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, Research and Development. 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, share-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 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.

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, cash equivalents and marketable securities of approximately $5.4 million as of December 31, 2023. 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, 2023. Disclosure controls and procedures include, without limitation, controls and 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 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 2024. 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, 2023, 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 required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fiscal year ended December 31, 2023 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, 2023. 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, 2023, 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, 2023, But Not Reported

None.

Trading Arrangements

Neil Hare, a member of the Company's Board of Directors, adopted a "Rule 10b5-1 trading arrangement" during the Company's fiscal quarter ended December 31, 2023. The trading arrangement, adopted December 29, 2023, and effective March 29, 2024, is intended to satisfy the affirmative defense of Rule 10b5-1(c). The trading arrangement will remain in place per its terms until the earlier to occur of September 29, 2024, completion of the sale of 45,044 shares of Longeveron Class A common stock, or upon the death or bankruptcy of Mr. Hare.

Other than Mr. Hare, none of the Company's other 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, 2023.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of February 1, 2024:

Name	Age	Position
Executive Officers		
Wa'el Hashad	61	Chief Executive Officer and Director
Joshua M. Hare, M.D.	61	Co-Founder, Chief Science Officer, Chairman and Director
Lisa Locklear	63	Chief Financial Officer and Treasurer
Paul Lehr, J.D.	56	General Counsel, and Secretary
Nataliya Agafonova	54	Chief Medical Officer
Non-Executive Employees		
Lisa McClain-Moss	53	Vice President of Manufacturing
Non-Employee Directors		
Khoso Baluch	66	Director
Neil E. Hare	54	Director
Douglas Losordo, M.D.[(1)]	66	Director
Jeffrey Pfeffer	77	Director
Cathy Ross	56	Director
Rock Soffer	42	Director
Ursula Ungaro	73	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, and is an elected Fellow of the American Heart Association. Dr. Hare has also served in numerous leadership roles at the American Heart Association 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, and 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 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 as well as its International Executive Director, overseeing Longeveron's international efforts and programs. 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 an Executive Director of GroundUP Music, 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 JD from University of Florida College of Law.

Nataliya Agafanova, M.D. (Chief Medical Officer ("CMO")) joined Longeveron on July 24, 2023 and serves as CMO. Prior to her time at 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 European Union 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

Lisa McClain-Moss (Vice President of Manufacturing) joined Longeveron in 2017. She has 20+ years of experience in the cell and gene therapy space including GMP cleanroom operations. During this time she was involved in the development, manufacturing and scale up of biopharmaceutical products including viral vectors such as vaccinia and retroviruses, H5N1 influenza seed stock for the WHO as well as seed stocks for multiple strains of influenza, rAAV, monoclonal antibodies and cell and tissue expansion and banking. From September 2007 to August 2017, she served as the Director of Manufacturing at Cognate Bioservices. While at Cognate she led manufacturing operations in a GMP environment as well as implementation of new client processes from technology transfer to finished final product. From March 1999 to August 2007, she served at St. Jude Children's Research Hospital starting with the production of vectors for clinical trials to Therapeutics Production Section Head providing oversight for GMP operations. From 1993 to 1999 she was a microbiologist at C. E. Kord Animal Diagnostic Laboratory providing diagnostic testing for multiple animal species. Ms. McClain-Moss received her B.S. in Biology/Microbiology from Tennessee Technological 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 US. 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 MBA from Cranfield School of Management.

Neil E. Hare, J.D. has served on Longeveron's Board of Directors since September of 2015. Mr. Hare is the founder and president of Global Vision Communications, LLC, a Washington, D.C.-based agency specializing in strategic communications, business development, branding and marketing. He is also a licensed attorney and is Of Counsel to the law firm of McCarthy Wilson LLP. Mr. Hare represents Fortune 500 companies, major trade associations, and Federal government agencies. He is an expert in small business policy, focusing on access to capital, and is a regular contributor to Forbes magazine. Previously, he served as vice president of Corporate Communications at the U.S. Chamber of Commerce, where he managed public policy awareness campaigns aimed at the Chamber's three million members on issues such as tax and regulatory reform, market driven health care, energy, free trade, and expanded transportation and infrastructure. Mr. Hare received a J.D. from American University's Washington College of Law and a B.A. in international relations from Tufts University.

Douglas Losordo, M.D. was elected to Longeveron's Board of Directors in February, 2021 as part of Longeveron's Corporate Conversion. Dr. Losordo has worked in the biotech industry developing cell-based therapies and small molecule drugs for over twenty years. Dr. Losordo is currently the CMO of Cadrenal Therapeutics(NASDAQ: CVKD) which became a public company in January 2023. Previously Dr. Losordo served as Global Head of Research and Development for American Regent, a private company in the US and subsidiary of Daiichi Sankyo, Executive Vice President, Global Head of Research and Development, Chief Medical Officer of Caladrius Biosciences Executive Vice President, Global Head of Research and Development, Chief Medical Officer of KBP Biosciences, a clinical-stage biopharmaceutical company dedicated to the development of a novel mineralocorticoid antagonist for treatment of refractory hypertension, Executive Vice President, Global Head of Research and Development, Chief Medical Officer of Caladrius Biosciences, a clinical-stage biopharmaceutical company dedicated to developing cellular therapies to reverse chronic disease. (NASDAQ: LSTA) Dr. Losordo has extensive knowledge of clinical, regulatory, manufacturing, supply chain and commercial factors involved in drug development as a result of his prior industry experience. Dr. Losordo's also previously served as a Professor of Medicine at NYU Langone Medical Center and Northwestern University's Feinberg School of Medicine. He received his M.D. from the University of Vermont College of Medicine, and his B.A. in Zoology from the University of Vermont.

Jeffrey Pfeffer was elected to Longeveron's Board of Directors in June 2023. Dr. Pfeffer is the Thomas D. Dee II Professor of Organizational Behavior at the Graduate School of Business, Stanford University where he has taught since 1979. He is the author or co-author of 16 books. Dr. Pfeffer received his B.S. and M.S. degrees from Carnegie-Mellon University and his Ph.D. from Stanford. Dr. Pfeffer currently serves on the advisory boards for Collective Health and Quorso, and on the boards of the nonprofit Quantum Leap Healthcare and the San Francisco Playhouse. In the past he has served on the boards of Resumix, Unicru, and Workstream (WSTM), all human capital software companies, Audible Magic, an internet company, SonoSite (SONO), a NASDAQ company designing and manufacturing portable ultrasound machines, Berlin Packaging, a Chicago-based supplier of packaging services, Portola Packaging, a private company making plastic bottle caps and bottles, and Actify, a software company.

Cathy Ross was elected to Longeveron's Board of Directors in February, 2021 as part of Longeveron's Corporate Conversion. Ms. Ross is a senior finance executive with over 30 years of experience. Since 2016, she has been a member of the Board of Directors and Chair of the Audit Committee of Fraud.Net, Inc., a privately held company that operates a real-time fraud detection and analytics platform. From 2006 to 2012, she was the Chief Financial Officer, President, and a member of the Board of Directors of MotherNature.com, a privately held online retailer and information source for vitamins, supplements, minerals and healthy products. In her role as Chief Financial Officer of MotherNature.com, she managed all aspects of accounting, budgeting and financial reporting. Prior to that, she served as Managing Director, Private Equity of Oasis Capital Partners, Vice President, Investment Banking and Public Offerings of Commonwealth Associates, Product Development and Marketing Manager of Ocwen Financial Corporation, and a Senior Credit Analyst for Chase Manhattan Bank. Ms. Ross earned a B.A. in Economics from Brown University in 1989.

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. was elected to Longeveron's Board of Directors on June 1, 2021. 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. Ms. Ungaro retired from the bench on May 31, 2021. Ms. Ungaro joined the law firm Boies Schiller Flexner LLP as a Partner following her retirement from the bench. Following her graduation with honors from the University of Florida School of Law in 1975 From 1987 to 1992, Ms. Ungaro served as a trial judge on the Eleventh Judicial Circuit of the State of Florida. 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.

Family Relationships

Joshua M. Hare and Neil E. Hare are brothers. There are no other family relationships among our directors or executive officers. Rock Soffer is the son of an investor in the Company who owns approximately 27% of total shares outstanding as of February 16, 2024.

Board Composition and Election of Directors

Our board of directors currently consists of nine 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 of directors will be determined from time to time by our board of directors.

Classified Board of Directors

In accordance with our certificate of incorporation and bylaws, our board of directors 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 directors are Rock Soffer and Neil E. Hare, and their terms will expire at our annual meeting of stockholders to occur in 2025;
- the Class II directors are Wa'el Hashad, Khoso Baluch and Jeffrey Pfeffer, and their terms will expire at our annual meeting of stockholders to occur in 2026; and
- the Class III directors are Joshua M. Hare, Douglas Losordo, Cathy Ross and Ursula Ungaro, and their terms will expire at the annual meeting of stockholders to occur in 2024.

Our certificate of incorporation and bylaws provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors 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 of directors 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 of Directors, elected by the 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 counsellor to executive management and oversees and monitors its performance.

Our Board of Directors held nine (9) meetings during 2023. Each director attended either in person or via teleconference at least 75% of the aggregate of all Board and applicable committee meetings during fiscal 2023 for the period in which they served as director. Although we do not have a formal policy regarding attendance by members of the Board of Directors at our annual meeting of stockholders, directors are encouraged to attend our annual meetings. One member of our Board of Directors was in attendance at our 2023 Annual Meeting of Stockholders, which was held virtually.

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

Audit Committee. Our Audit Committee is comprised of three members: Mr. Baluch (chair), Dr. Losordo and Ms. Ross. The Board of Directors 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 of directors' 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 of Directors 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. Ms. Baluch is the Audit Committee Chair, and the Board has determined that Ms. Ross qualifies as a financial expert, as that term is described in SEC regulations. The Audit Committee held five (5) meetings during 2023.

Compensation Committee. The Compensation Committee is comprised of four members: Ms. Ungaro (chair), Mr. Baluch, Mr. Pfeffer and Ms. Ross. The Board of Directors 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. Compensation Committee's responsibilities include reviewing and approving, or recommending for approval by the board of directors, the compensation of our Chief Executive Officer and our other executive officers; overseeing and administering our cash and equity incentive plans; reviewing and making recommendations to our board of directors 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, during 2022 to advise the Compensation Committee with respect to executive compensation benchmarking and compensation program structure. 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 five (5) meetings during 2023.

Governance and Nominating Committee. The Governance and Nominating Committee is comprised of three members: Dr. Losordo (chair), Mr. Pfeffer, and Ms. Ungaro. The Board of Directors has determined that all the members of the Governance and Nominating 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 of directors the persons to be nominated for election as directors and to each board committee; developing and recommending to our board of directors' corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time; and overseeing a periodic evaluation of our board of directors. The Board of Directors has adopted and approved a written charter for the Governance and Nominating Committee. A current copy of this charter is posted on our website at *http://www.longeveron.com* under the Investor Relations section. The Governance and Nominating Committee held six (6) meetings during 2023.

When considering a potential candidate for membership on our Board of Directors, our Governance and Nominating Committee considers relevant business and industry experience and demonstrated character and judgment. The Governance and Nominating Committee considers diversity in identifying candidates by generally seeking to achieve a diversity of occupational and personal backgrounds on the Board. However, the Governance and Nominating Committee has no formal policy regarding diversity. The Governance and Nominating Committee will consider stockholder nominations for directors submitted in accordance with the procedure set forth in Article II, Sections 5 and 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 Governance and Nominating Committee evaluates a candidate that is recommended for nomination for membership on our Board of Directors by a stockholder.

Finance Committee. The Finance Committee is comprised of four members: Mr. Baluch, Mr. Neil Hare, Ms. Ross, and Mr. Rock Soffer. The Finance Committee's purpose is to monitor, and to provide advice and counsel to the Board and the Company's management regarding the Company's asset mix, potential mergers and acquisitions, capital structure and policies, financial position and policies, financing activities and dividend policies. The Board of Directors has adopted and approved a written charter for the Finance Committee.

Board Member Independence

The Board of Directors has determined that each of Dr. Losordo, Ms. Ross, Ms. Ungaro, and Messrs. Baluch and Pfeffer are independent as defined in the Nasdaq Stock Market listing standards and applicable SEC regulations. Dr. Hare and Messrs. Soffer, Neil Hare, and Hashad have been determined not to be independent under relevant standards.

Board Member Diversity

The table below provides certain highlights of the composition of our current board members. Each of the categories listed in the below table has the meaning as it is used in Nasdaq Rule 5605(f).

Board Diversity Matrix (as of February 1, 2024)

Total number of directors	**9**			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	2	3		4
Part II: Demographic Background				
African American or Black				
Alaskan Native or Native American				
Asian				
Hispanic or Latinx				
Native Hawaiian or Pacific Islander				
White	1	3		
Two or More Races or Ethnicities	1			
LGBTQ+				
Did Not Disclose Demographic Background				4

Executive Sessions

Independent directors meet in executive session without the presence of our four 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 Governance and Nominating 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 Ethics

We have adopted a Code of Ethics that applies to all of our employees, executive officers and directors. We will provide a copy of the Code of 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 Ethics is posted on our website at *www.longeveron.com* under the Corporate Governance section. We intend to disclose any amendment to the Code of Ethics or waiver of a provision of the Code of 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 Annual Report on Form 10-K ("Form 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.

Hedging Prohibition

Our insider trading policy guidelines 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 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 director or a compensation committee (or other committee serving an equivalent function) of any entity that has one executive officers serving as a directors 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 2023 with the reporting requirements of Section 16(a) of the Exchange Act, with the exception of the following: (i) a Form 3 filed on July 13, 2023 reporting the initial securities ownership of Nataliya Agafonova, who was appointed

as Chief Medical Officer on July 1, 2023; (ii) two Forms 4 filed on June 9, 2023 reporting 3,247 shares withheld to satisfy tax obligations in connection with vesting of restricted stock award units by each of James Clavijo and Paul T. Lehr on June 2, 2023; (iii) a Form 4 filed on July 17, 2023 reporting 3,819 shares withheld to satisfy tax obligations in connection with vesting of RSUs by Wa'el Hashad on April 5, 2023; (iv) a Form 4 filed on August 1, 2023 reporting the award of 30,000 RSUs by Nataliya Agafonova on July 24, 2023; (v) a Form 4 filed on September 6, 2023 reporting 4,323 shares withheld to satisfy tax obligations in connection with vesting of RSUs by Wa'el Hashad on September 1, 2023; and (vi) a Form 4 filed on September 13, 2023 reporting the sale of Class A common stock Subscription Rights by Joshua Hare on various dates starting on August 25, 2023.

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 2023 and 2022. Our NEOs for 2023 were as follows:

- Wa'el Hashad, Chief Executive Officer (CEO)
- K. Chris Min., M.D., former Interim CEO and former Chief Medical Officer
- Lisa Locklear, Chief Financial Officer (CFO), Treasurer
- James Clavijo, former 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 of directors 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 — 2023 and 2022* on page 96 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. For more information, see *Summary Compensation Table — 2023 and 2022* on page 96 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 long-term equity incentive awards that incentivize those individuals to stay with us for long periods of time, which in turn should provide us with greater stability over such periods than we would experience without such awards.

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 $22,500 for calendar year 2023, and other testing limits. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2023 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. We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors 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 — 2023 and 2022

Name and principal position	Year	Salary ($)	Bonus ($)	Stock awards ($)[1]	Option awards ($)[2]	Nonequity incentive plan compensation ($)[3]	All other compensation ($)[4]	Total ($)
Wa'el Hashad, Chief Executive Officer	2023	431,474	—	633,500	161,500	309,167	40,918	1,576,559
K. Chris Min,	2023	104,167	—	—	—	—	180,529[6]	284,696
former interim CEO[5]	2022	261,111	—	1,957,505	593,374	69,670	43,628	2,925,288
Lisa Locklear, Chief Financial Officer, Treasurer	2023	161,539	—	132,400	—	75,000	11,840	380,779
Paul Lehr,	2023	372,346	—	—	—	130,250	51,459	554,055
General Counsel and Corporate Secretary	2022	324,659	—	349,200	105,699	81,165	42,435	983,158
James Clavijo,	2023	145,962	—	—	—	—	379,953[6]	525,915
Former CFO, Treasurer[7]	2022	319,319	—	349,200	—	72,284	33,755	774,558

(1) The values set forth in this column are based on the aggregate grant date fair values of Restricted Stock Units (RSUs) awards computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718. The grant date fair values of RSUs are computed based upon 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 of 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).

(3) Includes performance payouts for Company performance in 2023. The relevant performance measures for the annual performance awards were satisfied and thus are reportable in 2023, even though payments were made in 2024.
(4) Other compensation represents 401(k) matching and health insurance costs paid by the Company.
(5) Dr. Min, the Company's CMO from April 2022 through March of 2023, also served as the Interim CEO of the Company from June of 2022 through February of 2023. Amounts set forth herein include compensation paid for service as CMO as well as interim CEO in 2023. Dr. Min separated from the Company as interim Chief Executive Officer on March 1, 2023.
(6) Other compensation represents 401K matching, health insurance costs paid by the Company, separation amounts and unused vacation paid upon leaving the Company, and amounts for consulting services following his departure from the Company.
(7) Mr. Clavijo separated as full-time CFO of the Company effective June 9, 2023; thereafter, he continued to serve on a temporary basis pursuant to a consulting arrangement, until Ms. Locklear assumed the position of CFO on July 31, 2023.

Outstanding Equity Awards at Fiscal Year End 2023 Table

The following table sets forth information with respect to outstanding equity awards for each of our NEOs as of December 31, 2023. As a result of Dr. Min's and Mr. Clavijo's separation from service in 2023 as discussed below, neither NEO had any equity awards outstanding as of December 31, 2023.

	Options Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Exercisable	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 Chief Executive Officer	—	50,000[2]	$ 3.62	3/1/2033		
					125,000[3]	$ 170,000
Lisa Locklear, Chief Financial Officer, Treasurer	—	—	—	—	30,000[4]	$ 40,800
Paul Lehr, General Counsel and Corporate Secretary	34,375	15,625[5]	$ 3.62	7/20/2031		
	5,000	—[6]	$ 8.73	6/3/2032		
	9,994	12,849[7]	$ 4.30	11/16/2032		
					3,345[8]	$ 4,549
					13,334[9]	$ 18,134

(1) Based on a value of $1.36 per share, the closing market price of our common stock on December 29, 2023, the last trading day of 2023.
(2) The option, granted March 1, 2023, vests upon the one year anniversary of March 1, 2024.
(3) Performance Stock Unit granted on March 1, 2023, vests on March 1, 2024, and the number of shares to be paid will be determined based progress achieved against key performance indicators established on the grant date through the vesting date.
(4) RSUs granted on July 31, 2023, vests 25% on October 1, 2023, January 1, 2024, April 1, 2024, and July 1, 2023.
(5) The option, granted July 20, 2021, vested one-eighth on date of grant, with quarterly vesting thereafter.
(6) The option, granted June 3, 2022, was fully vested upon grant.
(7) The option, granted November 16, 2022, vests 25% on March 1, 2023 and then 6.25% each quarter thereafter.
(8) RSU granted January 29, 2021, vests at varying amounts over a three-year period.
(9) RSU granted June 3, 2022, vests in one-third increments annually.

Employment Agreements/Letters with our NEOs

Mr. Wa'el Hashad. Pursuant to the terms of the letter agreement ("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 $530,000 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 50,000 Restricted Stock Units,

which vested in quarterly installments on each of April 1, 2023, July 1, 2023, September 1, 2023, and December 31, 2023. Mr. Hashad will also be eligible to receive annual long-term equity incentive awards through 2026 consisting of 50,000 shares of time-based vesting stock options and up to 125,000 of performance share units, in accordance with the terms of the Longeveron 2021 Incentive Award Plan.

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, salary continuation for 12 months, COBRA coverage for 18 months, and 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 $400,000 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 40,000 Restricted Stock Units, which shall vest 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 100,000 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.

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, annual prorated cash bonus payment at target level, plus severance and reimbursement of COBRA premiums equal to three 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 $390,000 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 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, 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 prohibits 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.

Separation Severance Agreements/Letters with our Former NEOs

Dr. Christoper Min. On March 23, 2023, the Company entered into a Separation Agreement and General Release ("Separation Agreement") with Dr. Christoper Min that terminated his employment with the Company, effective March 31, 2023. Dr. Min's severance package under the Separation Agreement included (i) payment of an amount equal to $112,000, (ii) immediate acceleration and vesting of 40,000 Restricted Stock Units previously granted to him, and (iii) the cost of relinquishing his lease in Miami in the amount of $5,800. Additionally, Dr. Min agreed to release the Company from all past, present, and future claims related to the Separation Agreement, his benefits,

wages, employment and departure, except for a few customary exceptions such as enforcement of the Separation Agreement or reporting violations to applicable federal agencies. Dr. Min was given 21 days to review the terms of the Separation Agreement and seven days to revoke his acceptance after entering into the Separation Agreement. The Separation Agreement also included a "No Re-Employment" clause pursuant to which Dr. Min is prohibited from knowingly re-applying for employment with the Company. Dr. Min is also obligated to maintain the confidentiality of the Company's trade secret and Confidential Information (as defined in the Separation Agreement). Dr. Min subsequently entered into a consulting agreement where he was paid an hourly cash consulting fee until his services were no longer required by the Company. Dr. Min was no longer entitled to any benefits afforded by the Company to full or part-time employees and remained bound by Confidentiality/Nondisclosure and any other continuing obligations under terms of his employment agreement with the Company.

Mr. James Clavijo. On April 19, 2023, the Company entered into a Separation Agreement and General Release ("Separation Agreement") with Mr. James Clavijo terminating his employment with the Company, effective June 9, 2023. As part of Mr. Clavijo's severance package under the Separation Agreement, he received (i) severance amount equal to $275,000 was paid, (ii) accelerated vesting of 6,690 Restricted Stock Units previously granted to him, and (iii) three months payment for COBRA coverage. Additionally, Mr. Clavijo agreed to release the Company from all past, present, and future claims related to his employment and departure from the Company, except for a few customary exceptions such as the enforcement of the Separation Agreement or reporting any violation to applicable federal agencies. He was given 21 days to review the terms of the Separation Agreement and seven days to revoke his acceptance after entering into the Separation Agreement. The Separation Agreement also included a "No-Re-Employment" clause pursuant to which Mr. Clavijo is prohibited from knowingly re-applying for employment with the Company. Mr. Clavijo is also obligated to maintain the confidentiality of the Company's trade secret and Confidential Information (as defined in the Separation Agreement). Mr. Clavijo subsequently entered into a consulting agreement where he was paid an hourly cash consulting fee until his services were no longer required by the Company. Mr. Clavijo was no longer entitled to any benefits afforded by the Company to full or part-time employees and remained bound by Confidentiality/Nondisclosure and any other continuing obligations under terms of his employment agreement with the Company.

Potential Payments Upon Termination or Change in Control

The terms of the Company's 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 shareholders.

DIRECTOR COMPENSATION

Director Compensation Table. 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, 2023. 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]	$ 50,000	—	$ 13,128	$ 24,000[5]	$ 87,128
Khoso Baluch	$ 32,942	$ 17,100	$ 13,128	—	$ 63,170
Neil E. Hare	$ 39,000	—	$ 13,128	—	$ 52,128
Douglas Losordo, M.D.	$ 50,500	—	$ 13,128	—	$ 63,628
Jeffrey Pfeffer	$ 24,846	$ 17,100	$ 13,128	—	$ 55,074
Cathy Ross	$ 57,500	—	$ 13,128	—	$ 70,628
Rock Soffer	$ 42,500	—	$ 13,128	—	$ 55,628
Ursula Ungaro	$ 49,500	—	$ 13,128		$ 62,628

(1) Amounts reflect fees relating to calendar 2023.

(2) The values set forth in this column represent the aggregate grant date fair value, computed in accordance with FASB ASC Topic 718, Compensation — Stock Compensation (excluding the effect of forfeitures), of the onboarding restricted stock unit award granted to Messrs. Baluch and Pfeffer on June 9, 2023. A discussion of the relevant assumptions made in the valuation of this award may be found in Note 8 ("Equity Incentive Plan") of the footnotes to the Company's financial statements, in this Form 10-K for the fiscal year ended December 31, 2023. The number of shares of unvested restricted stock units outstanding as of December 31, 2023 was 2,500 for Messrs. Baluch and Pfeffer. There were no other RSUs for directors as of that date.

(3) The values set forth in this column represent the grant date fair value of the annual stock option award grant of 12,000 shares issued to each member of the Board of directors in December 2023.

(4) Amounts set forth herein reflect compensation received as a director of the Company. Dr. Hare also serves as the Chief Science Officer of the Company, and receives compensation for those services pursuant to the terms of a consulting agreement entered into with the Company in 2014. For additional information, see "Certain Relationships and Related Party Transactions."

(5) Estimated value relating to complimentary Bahamas Registry Trial treatments received by the individual.

Summary of Director Compensation

The director compensation program provides for annual retainer fees and/or long-term equity awards for our directors. For 2023, each director received an annual retainer of $35,000. A director serving as chairman of the board or lead independent director received an additional annual retainer of $15,000. Directors serving as the chairs of the audit, compensation and nominating and corporate governance, and finance committees received additional 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 annual retainers of $15,000, $10,000, $7,500 and $4,000, respectively. Annual equity grants, to be made following the Company's annual meeting of stockholders consist of stock options, with a grant date fair value of $15,000. Upon joining the board new directors receive initial equity grants of 5,000 shares of our Class A common stock, which shall be subject to vesting requirements.

Our board of directors 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 of directors or its authorized committee may make exceptions to this limit for individual directors in extraordinary circumstances, as the board of directors 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 16, 2024 (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 10,294,603 shares of Class A common stock and 14,839,993 shares of Class B common stock as of February 16, 2024.

Name of Affiliate	Class A Common Stock Shares	%	Class B Common Stock Shares	%	% of Total Voting Power[1]	% of Total Common Stock Beneficially Owned
Greater than 5% Holder:						
Donald M. Soffer	158,514	1.54%	6,535,223	44.04%	38.86%	26.63%
Lee Cohen Hare	—	—	2,984,828	20.11%	—	11.88%
Named Executive Officers and Directors						
Joshua M. Hare, M.D.[2]	375,265	3.65%	4,628,074	31.19%	45.49%	19.91%
Rock Soffer[4]	293,007	2.85%	410,094	2.76%	2.77%	2.80%
Neil E. Hare[3],[4]	60,658	*	—	—	*	*
Cathy Ross[4]	11,250	*	—	—	*	*
Ursula Ungaro[4]	6,250	*	—	—	*	*
Douglas Losordo[4]	6,250	*	—	—	*	*
Khoso Baluch	12,500	*	—	—	*	*
Jeffrey Pfeffer	12,500	*	—	—	*	*
Wa'el Hashad[5]	217,443	2.11%	—	—	*	*
Lisa Locklear[6]	26,824	*	—	—	*	*
Paul Lehr[7]	178,117	1.73%	—	—	*	*
Nataliya Agafonova[8]	20,786	*	—	—	*	*
C. Chris Min	—	*	—	—	*	*
James Clavijo	30,000	*	—	—	*	*
All Executive Officers and Directors as a Group (14 individuals)[9]:	1,250,850	12.15%	5,038,168	33.95%	48.96%	25.02%

* 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) Amount includes 38,750 stock options that are or may become exercisable within 60 days of February 16, 2024. Amount also includes 53,314 shares held by an affiliated entity. Dr. Hare disclaims beneficial ownership except to the extent of his pecuniary interest. Pursuant to a Voting Agreement and Proxy entered into between Dr. Hare and Lee Cohen Hare,

Dr. Hare's former spouse holds 2,984,828 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.

(3) Amount includes 894 shares of Class A common stock owned by Global Vision Communications, LLC, where Mr. Hare is the managing member. Mr. Hare disclaims beneficial ownership except to the extent of his pecuniary interest.

(4) Amount includes 1,250 stock options that are or may become exercisable within 60 days of February 16, 2024.

(5) Amount includes 50,000 stock options and 125,000 Performance Stock Units (PSUs") that may vest within 60 days of February 16, 2024.

(6) Amount includes 10,000 RSUs that may vest within 60 days of February 16, 2024.

(7) Amount includes 53,922 stock options that are or may become exercisable within 60 days of February 16, 2024.

(8) Amount includes 7,500 RSUs that may vest within 60 days of February 16, 2024.

(9) Amount includes an aggregate of 148,922 stock options, 17,500 RSUs and 125,000 PSUs that are or may become exercisable within 60 days of February 16, 2024.

Equity Compensation Plan Information

The following table summarizes information, as of December 31, 2023, 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]	675,236	$ 4.96	1,979,200[2]
Equity compensation plans not approved by security holders	—	—	—
Total	675,236	$ 4.96	1,979,200

(1) Represents outstanding awards pursuant to the Company's 2021 Plan. Represents shares of Class A common stock. Shares of Class B common stock are not authorized for issuance under the 2021 Plan.

(2) Shares of common stock that are subject to any award (e.g., options, restricted stock units, etc.) pursuant to the 2021 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, 2023 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, 2023:

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 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, 2023 and 2022, the Company had balances due to the CSO of $0.2 million and $0.1 million, respectively.

On March 27, 2015, the Company entered into a technology services agreement with Optimal Networks, Inc. (a related company owned by Dr. Joshua Hare's brother-in-law) for use of information technology services.

The technology services agreement was terminated as of April 14, 2023. Amounts paid were less than $0.1 million and $0.1 million, during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, the Company owed $0 and less than $0.1 million, respectively, pursuant to this agreement, which is included in accounts payable in the accompanying balance sheets.

We utilize Global Vision Communications, LLC, a service provider owned by a member of our board, Mr. Neil Hare, for public relations, information technology and web development services. Payment of invoices for services provided are made in cash or through the issuance of our common stock as mutually agreed to by the parties. Amounts paid were less than $0.1 million and $0.1 million during the years ended December 31, 2023 and 2022, respectively. As of both December 31, 2023, and 2022, the Company owed $0 to the related entity.

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 MSCs. 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, 2023 and 2022 pertaining to this agreement.

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, 2023 and 2022:

Fee Category	Fiscal 2023 Fees	Fiscal 2022 Fees
Audit Fees	$ 283,410	$ 115,000
Audit-Related Fees	—	—
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	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.
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.
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

Exhibit Number	Description of Exhibit
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
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
10.10	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.
10.14#	Employment Agreement between Longeveron Inc. and Wa'el Hasad, 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
10.16#	Letter Agreement between Longeveron, Inc. and Lisa Locklear, dated July 14,2023
10.17#	Letter Agreement between Longeveron, Inc. and Nataliya Agafonova, M.D. dated June 21, 2023
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

Exhibit Number	Description of Exhibit
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
16.1	Letter to Securities and Exchange Commission from MSL, P.A. dated March 25, 2022 incorporated by reference to Exhibit 16.1 to the Registrant's current report on Form 8-K filed March 25, 2022.
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
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	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).

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 27, 2024

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 27, 2024
/s/ Lisa A. Locklear Lisa A. Locklear	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	February 27, 2024
/s/ Joshua M. Hare Joshua M. Hare	Director	February 27, 2024
/s/ Khoso Baluch Khoso Baluch	Director	February 27, 2024
/s/ Neil E. Hare Neil E. Hare	Director	February 27, 2024
/s/ Rock Soffer Rock Soffer	Director	February 27, 2024
/s/ Douglas Losordo Douglas Losordo	Director	February 27, 2024
/s/ Cathy Ross Cathy Ross	Director	February 27, 2024
/s/ Jeffrey Pfeffer Jeffrey Pfeffer	Director	February 27, 2024
/s/ Ursula Ungaro Ursula Ungaro	Director	February 27, 2024

LONGEVERON, INC
FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Longeveron, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Longeveron, Inc. (the "Company") as of December 31, 2023 and 2022, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 a significant working capital deficiency, 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our 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 27, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 4,949	$ 10,503
Marketable equity securities	412	9,155
Prepaid expenses and other current assets	376	404
Accounts and grants receivable	111	218
Total current assets	5,848	20,280
Property and equipment, net	2,529	2,949
Intangible assets, net	2,287	2,409
Operating lease asset	1,221	1,531
Other assets	193	244
Total assets	$ 12,078	$ 27,413
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	638	1,751
Accrued expenses	2,152	650
Current portion of operating lease liability	593	564
Estimated lawsuit liability	—	1,398
Deferred revenue	506	506
Total current liabilities	3,889	4,869
Long-term liabilities:		
Long-term portion of operating lease liability	1,448	2,041
Total long-term liabilities	1,448	2,041
Total liabilities	5,337	6,910
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 June 30, 2023 and December 31, 2022	—	—
Class A common stock, $0.001 par value per share, 84,295,000 shares authorized, 10,251,764 shares issued and outstanding at December 31, 2023; 6,127,320 issued and outstanding at December 31, 2022	10	6
Class B common stock, $0.001 par value per share, 15,705,000 shares authorized, 14,855,539 shares issued and outstanding at December 31, 2023; 14,891,085 issued and outstanding at December 31, 2022	15	15
Additional paid-in capital	91,800	83,712
Stock subscription receivable	(100)	(100)
Accumulated deficit	(84,984)	(62,773)
Accumulated other comprehensive loss	—	(357)
Total stockholders' equity	6,741	20,503
Total liabilities and stockholders' equity	$ 12,078	$ 27,413

See notes to financial statements.

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

	Years ended December 31,	
	2023	**2022**
Revenues		
Grant revenue	$ 41	$ 282
Clinical trial revenue	668	940
Total revenues	709	1,222
Cost of revenues	488	725
Gross profit	221	497
Operating expenses		
General and administrative	11,401	8,119
Research and development	9,066	9,370
Sales and marketing	783	1,051
Total operating expenses	21,250	18,540
Loss from operations	(21,029)	(18,043)
Other (expense) and income		
Lawsuit expense	(30)	(1,398)
Other refundable tax credits	23	306
Other (expense) income, net	(377)	300
Total other expenses, net	(384)	(792)
Net loss	$ (21,413)	$ (18,835)
Dividend attributable to warrant down round feature	(798)	—
Net loss attributable to common stockholders	$ (22,211)	$ (18,835)
Basic and diluted net loss per share	$ (1.02)	$ (0.90)
Basic and diluted weighted average common shares outstanding	21,734,901	20,969,032

See notes to financial statements.

Longeveron Inc.
Statements of Comprehensive Loss
(In thousands)

	Years ended December 31,	
	2023	**2022**
Net loss	$ (21,413)	$ (18,835)
Other comprehensive loss:		
Net unrealized losses on available-for-sale securities	—	(357)
Total comprehensive loss	$ (21,413)	$ (19,192)

S*ee notes to 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 December 31, 2021	5,175,361	$ 5	$ 15,702,834	$ 16	$ (100)	$ 81,470	$ (43,938)	$ —	$ 37,453
Conversion of Class B common stock for Class A Common Stock	811,749	1	(811,749)	(1)	—	—	—	—	—
Class A common stock issued for RSUs vested	172,274	—	—	—	—	—	—	—	—
Class A common stock, held for taxes on RSUs vested	(32,438)	—	—	—	—	(304)	—	—	(304)
Class A common stock options exercised	374	—	—	—	—	2	—	—	2
Class A common stock issued for consulting						207			207
Equity-based compensation	—	—	—	—	—	2,337	—	—	2,337
Unrealized loss attributable to change in market value of available-for-sale securities	—	—	—	—	—	—	—	(357)	(357)
Net loss	—	—	—	—	—	—	(18,835)	—	(18,835)
Balance at December 31, 2022	6,127,320	$ 6	14,891,085	$ 15	$ (100)	$ 83,712	$ (62,773)	$ (357)	$ 20,503
Conversion of Class B common stock for Class A common stock	35,546	—	(35,546)	—	—	—	—	—	—
Class A common stock issued for RSUs vested	253,084	—	—	—	—	—	—	—	—
Class A common stock, held for taxes on RSUs vested	(52,227)	—	—	—	—	(174)	—	—	(174)
Class A common stock issued for stock rights offering, net of issuance costs of $325	108,497	—	—	—	—	—	—	—	—
Class A common stock issued in direct placements, net of issuance costs of $1,229	3,720,301	4	—	—	—	5,334	—	—	5,338
Class A common stock issued for prefunded warrants	59,243	—	—	—	—	98	—	—	98
Equity-based compensation	—	—	—	—	—	2,032	—	—	2,032
Unrealized loss attributable to change in market value of available-for-sale securities	—	—	—	—	—	—	—	357	357
Dividend attributable to down round feature of warrants	—	—	—	—	—	798	(798)	—	—
Net loss	—	—	—	—	—	—	(21,413)	—	(21,413)
Balance at December 31, 2023	10,251,764	$ 10	14,855,539	$ 15	$ (100)	$ 91,800	$ (84,984)	$ —	$ 6,741

See notes to financial statements.

Longeveron Inc.
Statements of Cash Flows
(In thousands)

	Years ended December 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (21,413)	$ (18,835)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	946	893
Interest earned on marketable securities	220	170
Equity-based compensation	2,032	2,167
Non-operating lawsuit expense	—	1,398
Non-cash write-off of intangible assets	290	—
Changes in operating assets and liabilities:		
Accounts and grants receivable	107	(164)
Prepaid expenses and other current assets	28	(122)
Other assets	51	(15)
Accounts payable	(1,113)	1,106
Deferred revenue	—	307
Non-operating lawsuit expense	(1,398)	—
Accrued expenses	1,502	(677)
Operating lease asset and liability	(254)	(197)
Net cash used in operating activities	(19,002)	(13,969)
Cash flows from investing activities:		
Proceeds from the sale of marketable securities	8,880	179
Acquisition of property and equipment	(301)	(569)
Acquisition of intangible assets	(393)	(287)
Net cash provided by investing activities	8,186	(677)
Cash flows from financing activities:		
Proceeds from the sale of private placements	5,338	—
Proceeds from warrants exercised	98	—
Proceeds from stock options issued	—	2
Equity issued for consulting services	—	(207)
Payments for taxes in RSUs vested	(174)	(304)
Net cash used in financing activities	5,262	(509)
Change in cash and cash equivalents	(5,554)	(15,155)
Cash and cash equivalents at beginning of period	10,503	25,658
Cash and cash equivalents at end of period	$ 4,949	$ 10,503
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Vesting of RSUs into Class A Common Stock	(777)	(1,780)
Dividend attributable to down round feature of warrants	798	—

See notes to financial statements.

1. Nature of Business, Basis of Presentation, and Liquidity

Nature of business:

Longeveron LLC was formed as a Delaware limited liability company on October 9, 2014 and authorized to transact business in Florida on December 15, 2014. On February 12, 2021, Longeveron LLC converted its corporate form (the "Corporate Conversion") from a Delaware limited liability company (Longeveron, LLC) to a Delaware corporation, Longeveron Inc. (the "Company," "Registrant," "Longeveron,", "we," "us," or "our"). The Company is a clinical stage biotechnology company developing 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 $21.4 million and $18.8 million for the years ended December 31, 2023 and 2022, respectively. In addition, as of December 31, 2023, the Company had an accumulated deficit of $85.0 million. The Company expects to continue to generate operating losses for the foreseeable future.

As of December 31, 2023, the Company had cash and cash equivalents of $4.9 million and marketable securities of $0.4 million. 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

1. Nature of Business, Basis of Presentation, and Liquidity (cont.)

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. To address the future funding requirements, in addition to planning future sales of equity securities, management has undertaken the following initiatives:

- On October 11, 2023 the Company entered into a securities purchase agreement with an institutional and accredited investor (the "Purchaser") relating to the registered direct offering and sale of an aggregate of 2,365,000 shares of the Company's Class A common stock, par value $0.001 per share and pre-funded warrants to purchase up to 59,243 shares of Class A common stock at an exercise price of $0.001 per share, at a purchase price of $1.65 per share and $1.649 per pre-funded Warrant (the "October 2023 Registered Direct Offering"), which Offering closed and was funded October 13, 2023.

  In a concurrent private placement, the Company also sold to the Purchaser unregistered Series A warrants to purchase up to an aggregate of 2,424,243 shares of its Class A common stock and unregistered Series B warrants to purchase up to an aggregate of 2,424,243 shares of its Class A common stock (the "Warrants")(the "October 2023 Private Placement" and collectively, with the October 2023 Registered Direct Offering, the "October 2023 Offering"). The Series A Warrants have an exercise price of $1.65 per share and have a term of five and one-half years from the date of issuance. The Series B Warrants have an exercise price of $1.65 per share and have a term of eighteen months from the date of issuance. The Series A and B warrants became exercisable upon stockholder approval on December 26, 2023, and each Warrant is exercisable for one share of Class A common stock. The net proceeds to the Company from the October 2023 Offering was approximately $3.4 million, after deducting placement agent fees and other offering expenses paid by the Company totaling approximately $0.6 million.

- On December 20, 2023 the Company entered into a securities purchase agreement with Purchaser relating to the registered direct offering and sale of an aggregate of 1,355,301 shares of the Company's Class A common stock, par value $0.001 per share, at a purchase price of $1.745 per share of common stock (the "December 2023 Registered Direct Offering"), which Offering closed and was funded on December 22, 2023.

  In private placement on December 22, 2023, concurrent with the December 2023 Registered Direct Offering, the Company also sold to the Purchaser unregistered long-term warrants to purchase up to an aggregate of 1,355,301 shares of its Class A common stock (the "December 2023 Private Placement", and together with the December 2023 Registered Direct Offering, the "December 2023 Offering") . The unregistered December 2023 Private Placement warrants have an exercise price of $1.62 per share, became immediately exercisable upon issuance, and expire on June 20, 2029. The purchaser may not exercise any portion of the December 2023 Private Placement warrants to the extent the Purchaser would own more than 4.99% of the Company's outstanding common stock immediately after the exercise. The Purchaser may decrease, upon at least 61 days' prior notice to the Company, increase this percentage with respect to the December 2023 Private Placement warrants. In no event shall such beneficial ownership limitation exceed 9.99%. and have a term of five and one-half years from the date of issuance. The net proceeds to the Company from the 2023 December 2023 Offering was approximately $2.0 million, after deducting placement agent fees and other offering expenses paid by the Company totaling approximately $0.3 million.

- the Company will attempt to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners;

- the Company plans to pursue potential partnerships for pipeline programs, however, there can be no assurances that it can consummate such transactions;

- the Company will continue to support its Bahamas Registry to generate revenue; and

1. Nature of Business, Basis of Presentation, and Liquidity (cont.)

- 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 National Institutes of Health ("NIH"), Alzheimer's Association, and Maryland Stem Cell Research Fund ("MSCRF"), and the Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies.

The Company's financial statements do not include any adjustments to the assets carrying amount, to the expenses presented and to the reclassification of the balance sheets items that could be necessary should the Company be unable to continue its operations.

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, 2022.

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 June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, "Financial Instruments — Credit Losses: Measurement of Credit Losses on Financial Instruments". The standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. The adoption of the standard as of January 1, 2023, did not have a material impact on the Company's financial statements.

In December 2023, the FASB issued ASU 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. We have not adopted ASU 2023-09 for our financial period ending December 31, 2023, and will continue to evaluate early adoption for our financial period ending December 31, 2024.

2. Summary of Significant Accounting Policies (cont.)

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:

Marketable securities at December 31, 2023 and 2022 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 $0.3 million and ($0.3) million for the years ended December 31, 2023 and 2022, respectively.

Inventory:

The Company will begin carrying inventory of its biological products on its balance sheets following commercial launch of such products. Inventory will consist of raw materials, biological products in process, and finished goods available for sale. The Company will determine its inventory values using the average cost method. Inventory will be valued at the lower of cost or net realizable value and will exclude units that the Company anticipates distributing for clinical evaluation. As of each of December 31, 2023 and 2022, all of the Company's biological products were anticipated to be distributed for clinical evaluation.

The Company does not currently carry any inventory for its biological products, as it has yet to launch a product for commercial distribution. Historically the Company's operations have focused on clinical trials and discovery efforts, and accordingly, costs of manufactured clinical doses of biological product candidates were expensed as incurred, consistent with the accounting for all other research and development costs. Once the Company begins commercial distribution, costs of all newly manufactured biological 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.

Accounts and grants receivable:

Accounts and grants receivable include amounts due from customers, granting institutions and others. The amounts as of December 31, 2023 and 2022 are deemed to be collectible and no amount has been recognized for doubtful accounts. MSCRF-TEDCO (defined below under Revenue Recognition) generally advance grant funds and therefore a receivable is not usually recognized. 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.

2. Summary of Significant Accounting Policies (cont.)

Accounts and grants receivable by source, as of (in thousands):

	December 31,	
	2023	**2022**
National Institutes of Health – Grant	$ 96	$ 218
Accounts receivable from customers	15	—
Total	$ 111	$ 218

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 no impairment of long-lived assets during the years ended December 31, 2023 and 2022.

2. Summary of Significant Accounting Policies (cont.)

Deferred revenue:

The unearned portion of advanced grant funds 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, 2023 and 2022, the Company recognized $0 and $0.1 million, respectively, 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 will be reversed when the funds are 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. Payment terms may vary depending on specific contract terms. There are no significant judgments affecting the determination of the amount and timing of revenue recognition.

Revenue by source (in thousands):

	Years ended December 31,	
	2023	**2022**
National Institute of Health – grant	$ 41	$ 164
Clinical trial revenue	668	940
MSCRF – TEDCO[(1)] – grant	—	118
Total	$ 709	$ 1,222

(1) Maryland Stem Cell Research Fund (MSCRF) — Maryland Technology Development Corporation (TEDCO)

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.

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.

2. Summary of Significant Accounting Policies (cont.)

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, 2023 and 2022 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, 2023 and 2022, 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 stock-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

2. Summary of Significant Accounting Policies (cont.)

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, 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

	Fair Value at December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. Treasury obligations	$ 97	$ —	$ —	$ 97
U.S. government agencies	—	1,250	—	1,250
Corporate and foreign bonds	—	7,808	—	7,808
Money market funds[(1)]	607	—	—	607
Accrued income	65	—	—	65
Total marketable securities	$ 769	$ 9,058	$ —	$ 9,827

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

As of December 31, 2023 and 2022, the Company reported accrued interest receivable related to marketable securities 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, 2023 and 2022, the Company recorded unrealized losses attributable to changes in marketable securities of $0 and $0.4 million, respectively. These unrealized losses were recorded on the balance sheets as accumulated other comprehensive loss.

As of December 31, 2023 and 2022, the amortized cost of these securities was $0.4 million and $9.4 million, respectively.

4. Property and equipment, net

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

	Useful Lives	**December 31, 2023**	**December 31, 2022**
Leasehold improvements	10 years	$ 4,328	$ 4,328
Furniture/Lab equipment	7 years	2,483	2,224
Computer equipment	5 years	120	46
Software/Website	3 years	38	38
Total property and equipment		6,969	6,676
Less accumulated depreciation and amortization		4,440	3,727
Property and equipment, net		$ 2,529	$ 2,949

Depreciation and amortization expense amounted to approximately $0.7 million for the years ended December 31, 2023 and 2022.

5. Intangible assets, net

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

Major components of intangible assets as of December 31, 2022, are as follows (in thousands):

	Useful Lives	Cost	Accumulated Amortization	Total
License agreements	20 years	**$ 2,043**	$ (685)	$ 1,358
Patent costs		**887**	—	887
Trademark costs		**164**	—	164
Total		**$ 3,094**	$ (685)	$ 2,409

Amortization expense related to intangible assets amounted to approximately $0.2 million for the years ended December 31, 2023 and 2022. During the year ended December 31, 2023, the Company wrote-off $0.3 million of abandoned patents that it was no longer pursuing in several jurisdictions.

Future amortization expense for intangible assets as of December 31, 2023 is approximately as follows (in thousands):

Year Ending December 31,	Amount
2024	$ 224
2025	224
2026	102
2027	61
2028	61
Thereafter	462
Total	$ 1,134

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, 2023, the operating lease asset and operating lease liability were approximately $1.2 million and $2.0 million, respectively. As of December 31, 2022, the operating lease asset and operating lease liability were approximately $1.5 million and $2.6 million, respectively.

Future minimum payments under the operating leases as of December 31, 2023 are as follows (in thousands):

Year Ending December 31,	Amount
2024	$ 682
2025	682
2026	682
2027	169
Total	2,215
Less interest (5% discount rate)	174
Present value of lease liability	$ 2,041

6. Leases (cont.)

During the years ended December 31, 2023 and 2022, the Company incurred approximately $0.9 million and $1.0 million, respectively, of total lease costs that are included in the general and administrative expenses in the statements of operations.

On July 1, 2020, the Company entered into a sublease agreement for a portion of its leased space for a one-year period ending June 30, 2021, with optional one-year renewal periods, and $10,000 in monthly payments. The sublease was terminated in the second quarter of 2022. For the year ended December 31, 2022, $27,000 was recognized as sublease income, due to the Company receiving $17,000 of equipment and $10,000 of security deposit forfeited.

7. Stockholders' Equity

Class A Common Stock

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, 2023, a total of 253,084 RSUs vested for Class A common stock shares. Of that amount, the Company withheld 52,227 Class A common stock shares to satisfy employee tax liabilities. During the year ended December 31, 2022, a total of 172,274 RSUs vested for Class A common stock shares. Of that amount, the Company withheld 32,438 Class A common stock shares to satisfy employee tax liabilities. The shares withheld are available for reissuance pursuant to the Company's 2021 Incentive Award Plan.

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 Dr. Hare. On May 24, 2023, these shares were issued to Dr. Hare.

On June 22, 2022, a total of 27,854 RSUs were granted to the Company's former Chief Executive Officer, Geoff Green, in exchange for $170,000 of compensation, as agreed upon in connection with his separation.

On April 18, 2023, the Company finalized the Separation Agreement dated March 31, 2023, for Dr. Christopher Min, the Company's former interim Chief Executive Office and Chief Medical Officer. In part for his agreement to a general release the Company agreed to pay Dr. Min: $112,000 as severance compensation and allowed for the immediate acceleration and vesting of 40,000 RSUs that were previously granted.

On April 19, 2023, the Company finalized the Separation Agreement effective June 9, 2023, for James Clavijo, the Company's former Chief Financial Officer ("CFO"). In part for his agreement to a general release the Company agreed to pay Mr. Clavijo $275,000 as severance compensation, three months of payment for COBRA insurance coverage and the immediate acceleration and vesting of 6,690 RSUs that were previously granted. Mr. Clavijo entered into a concurrent consulting agreement with the Company to continue as interim CFO until a permanent successor joined the Company. The consulting agreement has since expired.

On June 27, 2023, the Company filed a registration statement with the SEC to conduct a tradeable subscription rights offering for up to $30.0 million of shares of Class A common stock to its stockholders and holders of certain warrants to purchase common stock. On July 28, 2023, the Company filed a first amendment to the registration statement. On August 16, 2023, the registration statement was declared effective by the SEC, and on August 22, 2023, the Company launched the subscription rights offering at a subscription price of $3.00 per share of Class A common stock. On September 21, 2023, the subscription period for the rights offering of the Company expired. At the end of the subscription period, the Company sold 108,497 shares of its Class A common stock at a price of $3.00 per share. There were no net proceeds to the Company after deducting the $0.3 million of expenses associated with the rights offering.

7. Stockholders' Equity (cont.)

On October 11, 2023, the Company entered into a securities purchase agreement with an institutional and accredited investor (the "Purchaser") relating to the registered direct offering and sale of an aggregate of 2,365,000 shares of the Company's Class A common stock, par value $0.001 per share and pre-funded warrants to purchase up to 59,243 shares of Class A common stock at an exercise price of $0.001 per share, at a purchase price of $1.65 per share and $1.649 per pre-funded Warrant (the "October 2023 Registered Direct Offering"), which Offering closed and was funded October 13, 2023.

In a concurrent private placement, the Company also sold to the Purchaser unregistered Series A warrants to purchase up to an aggregate of 2,424,243 shares of its Class A common stock and unregistered Series B warrants to purchase up to an aggregate of 2,424,243 shares of its Class A common stock (the "Warrants")(the "October 2023 Private Placement" and collectively, with the October 2023 Registered Direct Offering, the "October 2023 Offering"). The unregistered Series A Warrants have an exercise price of $1.65 per share, became exercisable December 26, 2023, and have a term of five and one-half years from the date of issuance. The unregistered Series B Warrants have an exercise price of $1.65 per share, became exercisable December 26, 2023, and have a term of eighteen months from the date of issuance. The Series A and B warrants became exercisable upon stockholder approval on December 26, 2023, and each Warrant is exercisable for one share of Class A common stock. The net proceeds to the Company from the October 2023 Offering was approximately $3.4 million, after deducting placement agent fees and other offering expenses paid by the Company.

On December 20, 2023 the Company entered into a securities purchase agreement with an institutional and accredited investor (the "Purchaser") relating to the registered direct offering and sale of an aggregate of 1,355,301 shares of the Company's Class A common stock, par value $0.001 per share, at a purchase price of $1.745 per share of common stock (the "December 2023 Registered Direct Offering"), which Offering closed and was funded on December 22, 2023.

In a concurrent private placement on December 22, 2023, concurrent with the December 2023 Registered Direct Offering, the Company also sold to the Purchaser unregistered long-term warrants to purchase up to an aggregate of 1,355,301 shares of its Class A common stock (the "December 2023 Private Placement", and together with the December 2023 Registered Direct Offering, the "December 2023 Offering"). The unregistered December 2023 Private Placement warrants have an exercise price of $1.62 per share, became immediately exercisable upon issuance, expire on June 20, 2029, and have a term of five and one-half years from the date of issuance. The net proceeds to the Company from the December 2023 Offering was approximately $2.0 million, after deducting placement agent fees and other offering expenses paid by the Company.

During the year ended December 31, 2023, no stock options were exercised for shares of Class A common stock. During the year ended December 31, 2022, 374 stock options were exercised for shares of Class A common stock at an average exercise price of $5.73 for $2,143.

Class B Common Stock

In connection with the Corporate Conversion, 2,000,000 outstanding Series A and B units were converted into 15,702,834 shares of our unregistered 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, 2023, shareholders exchanged 35,546 shares of Class B common stock for 35,546 shares of Class A common stock. During the year ended December 31, 2022, shareholders exchanged 811,749 shares of Class B common stock for 811,749 shares of Class A common stock.

7. Stockholders' Equity (cont.)

Warrants

As part of the IPO, the underwriter received warrants to purchase 106,400 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 $12.00 per share. Total grant date fair value of warrants as of December 31, 2021 was approximately $0.5 million. During 2021, the underwriters assigned 95,760 of the warrants to its employees. As of December 31, 2023, 51,061 warrants have been exercised for Class A common stock shares at an exercise price of $12.00 for $612,732.

As part of the December 2021 PIPE Offering, the Company issued 1,169,288 warrants to investors ("Purchaser Warrants") to purchase up to a number of 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 $17.50 per share. The purchaser warrants are immediately exercisable, expire five years from the date of issuance and have certain downward pricing adjustment mechanisms, subject to a floor, as set forth in greater detail in the purchase warrants. In addition, the Company granted the underwriters warrants, under similar terms, to purchase 46,722 shares of Class A common stock, at an exercise price of $17.50 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 $5.25 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.

As part of the October 2023 Offering, the Company issued an aggregate of 2,424,243 Series A warrants and 2,424,243 Series B warrants to the purchaser to purchase up to a number of shares of Class A common stock. The Series A warrants have an exercise price of $1.65 per share and have a term of five and one-half years from the date of issuance. The Series B warrants have an exercise price of $1.65 per share and have a term of eighteen 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 underwriters warrants, under similar terms, to purchase 169,697 shares of Class A common stock, at an exercise price of $2.0625 per share.

As part of the December 2023 Offering, the Company sold unregistered long-term warrants to purchase an aggregate of 1,355,301 warrants to the purchase shares of Class A common stock. These unregistered warrants have an exercise price of $1.62 per share, became immediately issuable upon issuance, and expire on June 20, 2029. In addition, the Company granted the underwriters warrants, under similar terms, to purchase 94,871 shares of Class A common stock, at an exercise price of $2.1813 per share.

8. Equity Incentive Plan

RSUs

As part of the Company's IPO, the Company adopted and approved the 2021 Incentive Award Plan ("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.

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 Dr. Hare. On May 24,2023, these shares were issued to Dr. Hare.

On June 22, 2022, the Company granted $170,000 of separation compensation to Mr. Green (Mr. Green resigned as CEO effective June 1, 2022), which were converted into 27,854 RSUs. The RSU were issued based on the three-day average of the fair market value prior to the time of grant, June 22, 2022, of $6.10.

8. Equity Incentive Plan (cont.)

On June 3, 2022, the Company granted a bonus to each of Mr. Clavijo and Mr. Lehr in the form of RSUs. Mr. Clavijo and Mr. Lehr were each granted 40,000 RSUs each that vested one-third at the grant date, with the remaining two thirds vesting on the first- and second-year anniversary of the grant date. The RSU were issued based at fair market value at the time of grant, June 3, 2022, of $8.73.

On April 4, 2022, the Company appointed K. Chris Min, M.D., Ph.D. as its Chief Medical Officer. Dr. Min's employment agreement provided for annual base salary of $350,000, and he was eligible to receive a performance bonus equal to 30% of his base salary, prorated for his first year of employment. Dr. Min received a $60,000 signing bonus, with 50% of this amount paid in RSUs and 50% in stock options. Dr. Min also received two equity incentive awards: 150,000 RSUs and a stock option award exercisable for 50,000 shares. Each award was to vest 25% upon the first-year anniversary of his first day of employment with Longeveron, with 25% vesting thereafter on the second, third and fourth anniversaries of his employment. In each case, the vesting of the equity awards was to be subject to Dr. Min's continued service through the applicable vesting dates. RSUs were being expensed on a quarterly basis at the rate of $0.1 million for the quarterly vesting amount of 9,375 RSUs, with a price per share of $12.85 (the closing price of the Company's stock on April 4, 2022). Stock options were being expensed based upon a Black-Scholes calculation, the price per share to be expensed was $11.34 and a total cost of $0.6 million would be expensed ratably over 48 months. On April 18, 2023, the Company finalized the Separation Agreement dated March 31, 2023, for Dr. Min. In part for his agreement to a general release, the Company agreed to pay Dr. Min: $112,000 as severance compensation and allowed for the immediate acceleration and vesting of 40,000 RSUs that were previously granted.

On March 1, 2023, the Company granted the newly-hired Chief Executive Officer, Mr. Hashad a signing bonus of 50,000 RSUs, which vested in quarterly installments on each of April 1, 2023, July 1, 2023, September 1, 2023, and December 31, 2023. Mr. Hashad will also receive annual long-term equity incentive awards through 2026 consisting of 50,000 shares of time-based vesting stock options and up to 125,000 of performance share units "(PSUs"), in accordance with the terms of the Longeveron 2021 Incentive Award Plan.

On April 19, 2023, the Company finalized the Separation Agreement effective June 9, 2023, for James Clavijo, the Company's former Chief Financial Officer. In part for his agreement to a general release, the Company agreed to pay Mr. Clavijo $275,000 as severance compensation, three months of payment for COBRA insurance coverage and the immediate acceleration and vesting of 6,690 RSUs that were previously granted. Mr. Clavijo entered into a concurrent consulting agreement with the Company to continue as interim Chief Financial Officer until a permanent successor joined the Company. This agreement has since expired.

On June 9, 2023, the Company granted newly elected Board of Directors, Khoso Baluch and Jeffrey Pfeffer, 5,000 RSUs each. The RSUs vested 50% on the date of grant and will vest 25% on each of the next annual anniversary dates.

On July 24, 2023, the Company granted Nataliya Agafonova, Chief Medical Officer, a signing bonus of 30,000 RSUs, which vest in quarterly installments on each of July 24, 2023, October 1, 2023, January 1, 2024, and April 1, 2024.

On July 31, 2023, the Company granted Lisa Locklear, Executive Vice President and Chief Financial Officer, a signing bonus of 40,000 RSUs, which vest in quarterly installments on each of October 1, 2023, January 1, 2024, April 1, 2024, and July 31, 2024.

As of December 31, 2023 and 2022, the Company had 112,393 and 329,746, respectively RSUs outstanding (unvested).

8. Equity Incentive Plan (cont.)

RSU activity for the year ended December 31, 2023 was as follows:

	Number of RSUs
Outstanding (unvested) at December 31, 2022	329,746
RSUs granted	182,000
RSUs vested	(265,584)
RSU expired/forfeited	(133,769)
Outstanding (unvested) at December 31, 2023	112,393

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 four years and expire ten years from the date of grant. The 2021 Incentive Plan provides for equity grants to be granted up to 5% of the outstanding common stock shares.

The fair value of the options issued are estimated using the Black-Scholes option-pricing model and for 2023 have the following assumptions: 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%. For 2022, the following assumptions were used: a dividend yield of 0%; an expected life of 10 years; volatility of 95%; and risk-free interest rate based on the grant date ranging from of 1.23% to 3.68%. Each option grant made during 2023 and 2022, will be expensed ratably over the option vesting periods, which approximates the service period.

As of December 31, 2023, the Company has recorded issued and outstanding options to purchase a total of 437,843 shares of Class A common stock pursuant to the 2021 Incentive Plan, at a weighted average exercise price of $4.96 per share. Also, as of December 31, 2022, the Company has recorded issued and outstanding options to purchase a total of 470,191 shares of Class A common stock pursuant to the 2021 Incentive Plan, at a weighted average exercise price of $6.18 per share.

For the year ended December 31, 2023:

	Number of Stock Options
Stock options vested (based on ratable vesting)	160,107
Stock options unvested	277,736
Total stock options outstanding at December 31, 2023	437,843

For the year ended December 31, 2022:

	Number of Stock Options
Stock options vested (based on ratable vesting)	151,258
Stock options unvested	318,933
Total stock options outstanding at December 31, 2022	470,191

8. Equity Incentive Plan (cont.)

Stock Option activity for the year ended December 31, 2023 was as follows:

	Number of Stock Options		Weighted Average Exercise Price
Outstanding at December 31, 2022	470,191	$	7.07
Options granted	146,000	$	2.06
Options exercised	—		—
Options expired/forfeited	(178,348)	$	8.12
Outstanding at December 31, 2023	437,843	$	4.96

On December 21, 2023, the Company granted an award of 12,000 Class A common stock options to each of its non-employee directors (a total of 96,000 options). The stock option award has a four-year vesting period, vesting 25% per year, and has an exercise price of $1.25. Based upon a Black-Scholes calculation, the price per share to be expensed was $1.09 and a total cost of $0.1 million that would be expensed ratably over 48 months.

On March 1, 2023, the Company granted an award of 50,000 Class A common stock options to Mr. Hashad. The stock option award has a one-year vesting period, vesting on the first anniversary of the grant date, and has an exercise price of $3.62. Based upon a Black-Scholes calculation, the price per share to be expensed was $3.23 and a total cost of $0.2 million would be expensed ratably over 12 months.

On December 21, 2022, the Company granted an award of 5,000 Class A common stock options to each of its non-employee directors (a total of 45,000 options). The stock option award has a four-year vesting period, vesting 25% per year, and has an exercise price of $3.00. Based upon a Black-Scholes calculation, the price per share to be expensed was $2.67 and a total cost of $0.1 million that would be expensed ratably over 48 months.

On November 16, 2022, the Company granted an award of 22,843 Class A common stock options to Mr. Paul Lehr, General Counsel and Corporate Secretary. The stock option award has a four-year vesting period, vesting 25% per year, and has an exercise price of $4.30. Based upon a Black-Scholes calculation, the price per share to be expensed was $2.94 and a total cost of less than $0.1 million would be expensed ratably over 48 months.

On September 6, 2022, the Company granted an award of 10,000 Class A common stock options to an employee. The stock option award has a four-year vesting period, vesting 25% per year, and has an exercise price of $4.67. Based upon a Black-Scholes calculation, the price per share to be expensed was $4.15 and a total cost of less than $0.1 million would be expensed ratably over 48 months.

On June 3, 2022, the Company granted an award of 5,000 Class A common stock options to Mr. Lehr. The stock option award vested upon the grant date and has an exercise price of $8.73. Based upon a Black-Scholes calculation, the price per share to be expensed was $7.73 and a total cost of less than $0.1 million was expensed on the grant date.

On March 14, 2022, the Company granted an award of 22,000 Class A common stock options to employees. The stock option award has a four-year vesting period, vesting 25% per year, and has an exercise price of $5.94. Based upon a Black-Scholes calculation, the price per share to be expensed was $5.23 and a total cost of less than $0.1 million would be expensed ratably over 48 months.

On January 6, 2022, the Company granted awards of 84,825 Class A common stock options to employees. The stock option awards have four-year vesting periods, vesting 25% per year, and have an exercise price of $10.00. Based upon a Black-Scholes calculation, the price per share to be expensed was $8.78 and a total cost of $0.7 million would be expensed ratably over 48 months.

8. Equity Incentive Plan (cont.)

For the years ended December 31, 2023 and 2022, the equity-based compensation expense amounted to approximately $2.0 million and $2.3 million, respectively, which is included in the research and development and general and administrative expenses in the statements of operations for the years ended December 31, 2023 and 2022.

As of December 31, 2023, the remaining unrecognized equity-based compensation (which includes RSUs, PSUs and stock options) of approximately $1.5 million will be recognized over a weighted average time period of approximately 1.5 years.

9. Commitments and Contingencies

Master Services and Clinical Studies Agreements:

As of December 31, 2023, the Company had three active master services agreements with third parties to conduct its clinical trials and manage clinical research programs and clinical development services on behalf of the Company. The Company expects these agreements or amended current agreements to have total expenditures of approximately $1.1 million over the next two years.

As of December 31, 2022, the Company had two active master services agreements with third parties to conduct its clinical trials and manage clinical research programs and clinical development services on behalf of the Company.

Consulting Services Agreement:

On November 20, 2014, the Company entered into a ten-year consulting services agreement with Dr. Joshua Hare, its 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. As of December 31, 2023 and 2022, the Company had accrued balances due to the CSO of approximately $0.1 million and less than $0.1 million, respectively, included in accrued expenses and approximately $0.1 million for both years included in accounts payable in the accompanying balance sheets.

Technology Services Agreement:

On March 27, 2015, the Company entered into a technology services agreement with Optimal Networks, Inc. (a related company owned by Dr. Joshua Hare's brother-in-law) for use of information technology services. The technology services agreement was terminated as of April 14, 2023. As of December 31, 2023 and 2022, the Company owed $0 and less than $0.1 million, respectively, pursuant to this agreement, which is included in accounts payable in the accompanying balance sheets.

9. Commitments and Contingencies (cont.)

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 MSCs for Aging-related Frailty used at the Human-induced pluripotent stem cell-derived MSCs (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 $365,000 to UM, and as of December 31, 2023 and 2022, in the accompanying balance sheets, we had accrued $50,000 in milestone fees payable to UM for both years and $15,000 and $30,000, respectively, for patent related reimbursements based on the estimated progress to date.

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, 2023 and 2022 pertaining to this agreement.

9. Commitments and Contingencies (cont.)

Other Royalty

Under the grant award agreement with the Alzheimer's Association, the Company may be required to make revenue sharing or distribution of revenue payments for products or inventions generated or resulting from this clinical trial program. The potential payments, although not currently defined, could result in a maximum payment of five times (5x) the award amount of $3.0 million.

Contingencies — Legal

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 $131,000 and $88,000 to the Plan during the years ended December 31, 2023 and 2022, 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, 2023 and December 31, 2022 (in thousands):

	2023	2022
Deferred tax assets:		
Net operating loss carry forwards	$ 7,790	$ 6,103
ASC 842 Lease liability	514	690
Equity based compensation	201	1,993
Fixed assets	—	435
Intangible assets	106	45
Capitalized research & development expenses	3,830	1,753
Tax credits	1,258	
Accrual to cash adjustment	—	911
Other	468	—
Total deferred tax assets	14,167	11,930
Valuation allowance	(13,776)	(11,524)
Deferred tax assets, net of valuation allowance	391	406
Deferred tax liabilities:		
ASC 842 Right-of-use asset	(307)	(406)
Depreciation and amortization	(84)	—
Total deferred tax liabilities	(391)	(406)
Deferred tax assets and liabilities, net of valuation allowance	$ —	$ —

As of December 31, 2023, the Company had NOL carryforwards for federal purposes of approximately $30.9 million, all of which have no expiration. The Company also had state NOL carryforwards of approximately $29.9 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, 2023 and 2022 were as follows:

	2023	2022
Federal tax at statutory rate	21.0%	21.0%
State tax benefits, net of federal benefit	4.2	6.9
Other	1.6	0.8
Change in valuation allowance	(26.7)	(28.7)
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, 2023, 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, 2023 and 2022.

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 stock-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,	
	2023	**2022**
RSUs	112	330
PSUs	125	—
Stock options	438	470
Warrants	7,740	1,271
Total	8,415	2,071

13. Subsequent Events

In line with the Company's 2024 strategic direction to focus its resources on HLHS and AD and manage its cash spend, the Company decided to discontinue its previously disclosed clinical trial in Japan to evaluate Lomecel-B™ for Aging-related Frailty.

On February 21, 2024, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse stock split of its outstanding shares of Class A common stock and Class B common stock at a ratio, ranging from one-for-five (1:5) to one-for-fifteen (1:15), with the exact ratio to be set within that range at the discretion of its Board of Directors without further approval or authorization of its stockholders. The date of the reverse stock split and the ratio has not yet been determined.

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

FORM 10-K/A
(Amendment No. 1)

(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, 2023

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
Common Stock, par value $0.001	**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 $19,016,000 as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter).

As of February 23, 2024, the registrant had 10,294,603 shares of Class A common stock, $0.001 par value per share, and 14,839,993 shares of Class B common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE. None

Auditor Name:	Auditor Location:	Auditor Firm ID:
Marcum LLP	Hartford, CT	688

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this "Amendment") amends the Annual Report on Form 10-K of Longeveron Inc. (the "Company") for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2024 (the "Original Form 10-K"). This Amendment is being filed solely to correct scrivener's errors in the Original Form 10-K under Part I, Item 1: Business in the description of the Company's owned intellectual property concerning (i) Mesenchymal stem cells as vaccine adjuvants and methods for using the same ("Patent Family 1") and (ii) methods of using human mesenchymal stem cells to effect cellular and humoral immunity ("Patent Family 2"). The Original Form 10-K erroneously disclosed that the Company (a) *owned and was continuing to prosecute and maintain* a U.S. patent application in Patent Family 1, (b) had one allowed patent application and one pending patent application in Japan in Patent Family 1 and (c) *received a notice of allowance* for certain patent applications in Patent Family 2. This Amendment corrects this disclosure to correctly indicate that the Company (x) *received a notice of allowance* for a U.S. patent application in Patent Family 1, (y) has two *pending* patent applications in Japan in Patent Family 1 and (z) *owns* certain patent applications in Patent Family 2.

As required under SEC rules, this Amendment sets forth the complete text of Part I, Item 1: Business, as amended and restated. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), new certifications by the Company's principal executive officer and principal financial officer are filed herewith as exhibits to this Amendment pursuant to Rules 13a-14(a) and 15(d)-14(a) of the Exchange Act and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350).

Except as described above, no other changes have been made to the Original Form 10-K, and this Amendment does not otherwise amend, update or change the financial statements or other disclosures in the Original Form 10-K. This Amendment speaks as of the filing date of the Original Form 10-K and does not (i) reflect events, results or developments that occurred or facts that became known after the filing date of the Original Form 10-K or (ii) modify or update those disclosures affected by subsequent events, results, developments or facts. Among other things, forward-looking statements made in the Original Form 10-K have not been revised to reflect events, results or developments that occurred or facts that became known to us after the date of the Original Form 10-K, and such statements should be read in conjunction with our filings with the SEC subsequent to the Original Form 10-K. This Amendment should be read in conjunction with the Company's other filings with the SEC subsequent to February 27, 2024.

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 the tissue repair programs include the stimulation of new blood vessel formation, modulation of the immune system, 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.

In November of 2023, Longeveron received notice from the World Health Organization ("WHO") that "laromestrocel" has been selected as the proposed International Nonproprietary Name for Longeveron's Lomecel-B™ product. Assuming that there are no third-party objections to that name, the name will be recommended for adoption by the WHO. Longeveron will adopt that name if it is recommended by the WHO.

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 this data shows 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 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 improvement in HLHS survival following the Phase 1 ELPIS I clinical trial has resulted in acceptance by the American Heart Association ("AHA") for a poster presentation at an AHA meeting in November 2023. The ELPIS I trial showed 100 percent survival in children up to 5 years of age after receiving Lomecel-B™, compared to a 20 percent mortality rate observed from historical control data. Based on these findings, the U.S. Food and Drug Administration (the "FDA") granted Lomecel-B™ both Rare Pediatric Disease (RPD") Designation and Orphan Drug Designation ("ODD") for treatment of infants with HLHS. 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 functional and clinical benefit of Lomecel-B™ as part of standard-of-care treatment in HLHS patients.

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1 Sunjay Kaushal, MD, PhD, Joshua M Hare, MD, Jessica R Hoffman, PhD, Riley M Boyd, BA, Kevin N Ramdas, MD, MPH, Nicholas Pietris, MD, Shelby Kutty, MD, PhD, MS, James S Tweddell, MD, S Adil Husain, MD, Shaji C Menon, MBBS, MD, MS, Linda M Lambert, MSN-cFNP, David A Danford, MD, Seth J Kligerman, MD, Narutoshi Hibino, MD, PhD, Laxminarayana Korutla, PhD, Prashanth Vallabhajosyula, MD, MS, Michael J Campbell, MD, Aisha Khan, PhD, Eric Naioti, MSPH, Keyvan Yousefi, PharmD, PhD, Danial Mehranfard, PharmD, MBA, Lisa McClain-Moss, Anthony A Oliva, PhD, Michael E Davis, PhD, 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 Alzheimer's disease 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. Notably, 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 Alzheimer's disease score ("CADS") for both the low-dose Lomecel-B™ group and the pooled treatment groups compared to placebo. Other doses also showed promising results in slowing/prevention of disease worsening. Additionally, a statistically significant improvement versus placebo was observed in the 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"). These findings support both the safety and potential therapeutic benefit of Lomecel-B™ in managing mild Alzheimer's disease, and we believe lays a strong groundwork for subsequent trials in this indication.

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. Our preliminary clinical data suggest that Lomecel-B™ may potentially address these problems through multiple potential mechanisms of action ("MOAs") that simultaneously target key aging-related processes. We are using Lomecel-B™ in registry trials in The Bahamas as part of the real-world data generation for the aging population.

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 magnetic resonance imaging ("MRI") demonstrated whole brain volume loss slowed accompanied by significant preservation of left hippocampal volume 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. We are actively in pursuit of a partnership to propel this initiative forward.

- Limited focus on our international program. In line with the Company's strategic direction for 2024 and moving forward to focus on HLHS and AD as set forth previously, the Company has 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 2024

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

Indication	Geography	Phase 1	Phase 2	Phase 3
HLHS	U.S.			
Aging-related Frailty*	U.S.			
Alzheimer's disease	U.S.			

Figure 1: Lomecel-B™ clinical development pipeline

* Not currently active for 2024

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. 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 converts the normally 4-chamber heart into a 3-chamber one with a single ventricle (the right ventricle) supporting 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 2 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 over 50% enrolled and is funded in part by the NHLBI/NIH. While we cannot predict a specific time when the trial will be fully enrolled, the current plan is that enrollment will be completed in 2024.

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. In addition to the 12-month follow-up evaluation on ELPIS, we continue to follow these patients on an annual basis. As of February 2024, all 10 patients have survived (100%), seven of the patients have reached the age of five and have successfully undergone the third-stage surgery, and two of them have reached the age of six years old, all without the need for a heart transplantation. Based on historical data, over 15% of patients would be expected to have received a heart transplant or have died within three years after the second-stage surgery, rising to nearly 20% by five years. We intended to continue to follow-up with these patients for up to an additional five years, until all patients reach ten years of age.

We are prosecuting a number of patent applications relating to the administration of mesenchymal stem cells for treating HLHS in Canada, Japan, Taiwan, the United States and the Bahamas, with applications having also been ordered for filing in Australia, China, South Korea, and the European Patent Office.

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]. As previously indicated, we are actively in pursuit of a partnership to propel our AD initiative forward.

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 multicenter, 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 multicenter, 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.

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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*.

We are prosecuting or have sent filing instructions for a number of patent applications relating to the administration of MSC for Aging-related Frailty in Australia, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, Singapore, South Korea, New Zealand, Taiwan, the Bahamas and 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.

Our lead product, Lomecel-B™, consists of human allogeneic bone-marrow derived MSCs 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 bone marrow supply contracts in place with two suppliers: the Oklahoma Blood Institute and All Cells, with a potential third vendor in process. These suppliers provide adequate bone marrow for our current and anticipated needs; however, if one or both 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 product to be a novel therapeutic 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.

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 1,550 worldwide as of January 2024.

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

Name	Corporate Headquarters	Clinical stage pipeline indication(s)
Athersys, Inc.	U.S.	Ischemic stroke; ARDS; GvHD; Acute Myocardial Infarction
BioCardia, Inc.	U.S.	Heart failure; Acute myocardial infarction
BrainStorm Cell Therapeutics	U.S.	ALS; MS
Lisata Therapeutics	U.S.	Coronary microvascular dysfunction; Critical limb ischemia; Diabetic kidney disease
CorestemChemon	South Korea	ALS (Commercial in South Korea); Lupus
Cynata Therapeutics	Australia	GvHD
Healios K.K.	Japan	Ischemic stroke; ARDS
Medipost	South Korea	Osteoarthritis (commercial); BPD; AD
Mesoblast Ltd.	Australia	Heart failure, low back pain, GvHD; ARDS; Crohn's Disease, HLHS
Pluri, Inc.	Israel	CLI; ARDS; ARS; GvHD
ReNeuron	U.K.	Ischemic stroke; Retinitis pigmentosa
SanBio Co., Ltd.	Japan	Ischemic stroke; Traumatic brain injury
Stemedica Cell Technologies	U.S.	Ischemic stroke; heart failure; AD

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.

Aging Frailty Competitive Intelligence Research

Per ClinicalTrials.gov, as of February 18, 2024, there were 107 clinical trials in Aging Frailty listed on the site including all stages (ongoing, completed, terminated, withdrawn) and all interventions. Of the 107 listed studies, there were 29 studies listed which are currently enrolling patients with aging frailty. Among those, allogeneic bone-marrow-derived mesenchymal stem cell were listed as an intervention in three studies:

- "A Study to Evaluate Allogenic Bone-Marrow Mesenchymal Stromal Cell Product StromaForte in Aging Frailty Patients", sponsored by Cellcolabs Clinical SPV Limited. This phase I/IIa study in frail patients is designed to assess the safety of intravenous human allogenic bone marrow-derived mesenchymal stromal cell product StromaForte by reporting the number of adverse events assessed by Common Terminology Criteria. 12 male and female patients aged 60 to 85 years will be enrolled. The study initiated on October 2, 2023, with estimated completion date November 28, 2024. The study is currently enrolling patients in United Arab Emirates.

- "Safety of Cultured Allogeneic Adult Umbilical Cord Derived Mesenchymal Stem Cell Intravenous Infusion for Aging Frailty", sponsored by The Foundation for Orthopedics and Regenerative Medicine. This trial will study the safety and efficacy of intravenous infusion of cultured allogeneic adult umbilical cord derived mesenchymal stem cells for the treatment of Aging Frailty. The plan is to enroll 20 patients. The study initiated on August 24, 2021 and estimated completion study date is December 1, 2027.
- "A Study of Human Allogeneic Bone-marrow-derived Mesenchymal Stromal Cell Product (StromaForte) in Patients With Aging Frailty", sponsored by Cellcolabs Clinical LTD. The goal of this phase I/II clinical trial is to evaluate the safety and tolerability of intravenous infusion of human allogeneic bone-marrow-derived mesenchymal stromal cell product StromaForte in patients with aging frailty. The main questions it aims to answer are: 1) To assess the safety and tolerability after 28 days of injection by reporting the number of adverse events assessed by Common Terminology Criteria For Adverse Events ("CTCAE") 2) Observe the change in inflammatory markers from baseline to six months (baseline to 28, 84, and 168 days post-infusion.). The study was initiated on October 9, 2023 and the estimated date of completion is January 10, 2025.

Alzheimer's Disease Competitive Intelligence Research

Per ClinicalTrials.gov, as of February 18, 2024, there were 3,334 studies listed on the site studying Alzheimer's disease, including all stages (ongoing, completed, terminated, withdrawn) and all interventions. Among those, 401 studies were listed with Alzheimer's disease as an indication and stem cells as an intervention. Seventeen of them were listed to conduct clinical studies with mesenchymal stem cells in all stages and only one of them is currently enrolling patients on the study:

- "Allogeneic Human Mesenchymal Stem Cells for Alzheimer's Disease", Phase 2 study, sponsored by Stemedica Cell Technologies, Inc. The main goals of this study are 1) To assess the safety and tolerability of ischemia-tolerant allogeneic human mesenchymal stem cells ("hMSCs") manufactured by Stemedica versus placebo administered intravenously to subjects with mild to moderate dementia due to Alzheimer's disease and 2) To assess the preliminary efficacy of hMSCs versus placebo in subjects with Alzheimer's-related dementia, as evidenced by neurologic, functional, and psychiatric endpoints. This study planned to enroll 40 patients in United States, California. The study was initiated on June 1, 2016, and the estimated study completion date is December 31, 2024.

There are many other pharmaceutical and biotechnology companies that are conducting clinical trials of various therapeutics for the treatment of AD.

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.

By letter dated November 20, 2023, Longeveron was informed by the WHO that "laromestrocel" has been selected as the proposed International Nonproprietary Name for Longeveron's Lomecel-B™ product. Assuming that there are no third-party objections to that name, the name will be recommended for adoption by the WHO. Longeveron will adopt that name if it is recommended by the WHO.

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 MSCs 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™ MSCs are approved by the FDA, third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. Our ability to deter and, if necessary, to stop third parties from making, using, selling, offering to sell or importing our 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, or 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 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 MSCs in a subject that exhibits "inflammaging." In this family we received a notice of allowance for our U.S. patent application, and we have two pending applications in Japan, one pending application in Australia, and one pending application in the European Patent Office. Another European Patent Office application has been allowed, and pending conclusion of the opposition period is planned to be 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 one pending U.S. patent application, and 14 patent applications outside of the U.S. (in 12 jurisdictions). The Chinese counterpart of the application has been allowed. Patents have issued in Japan and Taiwan, and a patent registration has issued 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. In addition to the applications in Taiwan and The Bahamas, PCT national or regional phase applications were filed in the U.S., Australia, Canada, China, the European Patent Organization, Israel, Japan, South Korea, New Zealand, Singapore, South Africa, and Hong Kong. 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 won and are continuing to maintain a patent registration in the Bahamas. The U.S., Japanese, and European properties are a national or regional phase applications based on a PCT application filed on June 15, 2018 and claiming priority to a U.S. provisional application filed in June 2017. The registration in the Bahamas claims priority to that same provisional application but was not filed using the PCT. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in June 2038. Longeveron has elected to take no further action and to allow to become abandoned, properties in the family in Australia, Canada, China, Hong Kong, Israel, Korea, Singapore, South Africa, South Korea, Taiwan, and New Zealand.

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

Use of Mesenchymal Stem Cells in Treatment of Juvenile Hypoplastic Left Heart Syndrome. This patent family is directed to treatment of HLHS with allogeneic MSCs. In this family we own pending applications in Taiwan, the Bahamas, and the PCT. These applications share a common priority date of July 2021. National and regional phase applications based on pending PCT application, have been filed or are expected to be filed in Australia, Canada, China, the European Patent Office, Japan, South Korea, Taiwan, and the United States. 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 MSCs 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 or are expected to be 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 MSCs to treat AD. We own pending patent applications in Australia, the Bahamas, South Korea, Singapore, South Africa, Israel, Canada, Hong Kong, New Zealand, China, Japan, the European Patent Office, and the United States. Those applications claim priority to three separate U.S. provisional applications, the earliest of which was filed in September 2020. If issued, and assuming that all maintenance and annuity fees are paid, patents arising from these applications are expected to expire in September 2041.

License Agreements and Strategic Collaborations

The University of Miami ("UM")

On November 20, 2014, we entered into an Exclusive License Agreement with UM (the "UM License") for the use of certain Aging-related frailty-related MSC technology rights developed by our Chief Science Officer, Dr. Joshua Hare, at UM. The UM License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how specifically related to the development of the culture-expanded MSCs for aging-related frailty used at the Interdisciplinary Stem Cell Institute of UM ("IMSCs"), all standard operating procedures used to create the 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 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 HLHS IND with ckit+ cells; and (b) UMP-438 titled "Method of Determining Responsiveness to Cell Therapy in Dilated Cardiomyopathy."

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, 2023, we had accrued $50,000 in milestone fees payable to UM.

CD271

On December 22, 2016, we entered into a worldwide exclusive license agreement with JMH MD Holdings ("JMHMD"), an affiliate 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 $25,000 for each of the years ended December 31, 2023 and 2022, 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.

Trademarks

We have registered trademarks or applied for registered trademarks for "Longeveron" in the following jurisdictions. We have begun to phase 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"	"LMSC"
The Bahamas		Registered	Closed
Brazil		Registered	
Canada		Registered	
China		Registered	Registered
European Union		Registered	
Hong Kong		Registered	
India		Registered	
Japan		Registered	Registered
South Korea		Registered	
Morocco		Registered	Registered
Panama		Registered	
Switzerland		Registered	
Taiwan		Registered	
U.S.	Allowed	Allowed	Registered
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.

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 access to certain data 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:

- 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. 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 filing of a priority BLA. 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. 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, or 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 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.

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 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. Receiving a fast-track designation is not the same as receiving FDA product approval.

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. 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. 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 adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch 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.

In addition to the potential award of a seven-year ODE 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 are also exempt from program fees otherwise required under the PDUFA. For fiscal year 2024, the application fee for a new drug or biologic requiring clinical studies is $4,048,695, and the program fee for approval of prescription drugs and biologics is $416,734.

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 agencies 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.

Other Healthcare Laws

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, False Claims Act, Consumer Fraud Act, 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, 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.

Japanese Laws and Regulations

There are two primary Acts in Japan that regulate regenerative medicine development and offer two pathways to market for regenerative medicine therapeutic candidates: The Act pm the Safety of Regenerative Medicine ("ASRM") and the Pharmaceuticals and Medical Devices Act ("PMDA").

The ASRM allows physicians to provide cellular therapies to patients through an application process that is regulated by the Japanese Ministry of Health, Labor and Welfare ("MHLW"). Manufacturers of cell and gene therapy products wishing to utilize this pathway must identify and work with a partner clinic or hospital which enables the clinic to act as the distributor, with the manufacturer receiving a fee or a royalty, for example.

The PMDA includes special treatment for regenerative medicine products and identifies them as a stand-alone medical category with a novel "conditional approval" system. Sponsors seeking manufacturing approval need to provide clinical data to show that the product does not have any major safety concerns, clinical data to demonstrate "probable" efficacy, and satisfy established chemistry, manufacturing and controls criteria.

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, 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.

Human Capital Management

As of December 31, 2023, we had 23 full-time employees, one part-time employee and one full-time consultant. Among those, four had M.D. or Ph.D. degrees, two are Certified Public Accountants, and one has a J.D. degree. Of these full-time employees and consultants, 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.

See Part III of the Original 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 under the symbol "LGVN".

Part IV

Item 15. Exhibits and Financial Statements Schedules

a. (1) Financial Statements:

Not applicable.

(2) Financial Statement Schedules

Not applicable.

Exhibit Number	Description of Exhibit
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
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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

March 11, 2024

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

SIGNATURES

In accordance with the Exchange Act, this Amendment No. 1 to the Annual Report of Longeveron Inc. on Form 10-K/A 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)	March 11, 2024
/s/ Lisa A. Locklear Lisa A. Locklear	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 11, 2024

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Corporate Information

EXECUTIVE MANAGEMENT TEAM

WA'EL HASHAD
Chief Executive Officer and DIRECTOR

JOSHUA M. HARE, MD, FACC, FAHA
Chief Science Officer and Chairman

LISA LOCKLEAR
Chief Financial Officer

NATALIYA AGAFONOVA, MD
Chief Medical Officer

PAUL LEHR, JD
General Counsel and Secretary

BOARD OF DIRECTORS

JOSHUA M. HARE, MD, FACC, FAHA-Chairman

WA'EL HASHAD, CEO

KHOSO BALUCH

NEIL HARE, JD

RICHARD KENDER

DOUGLAS LOSORDO, MD

ROCK SOFFER

URSULA UNGARO, JD

INVESTOR RELATIONS

Inquiries and requests for information, including copies of Longeveron's Annual Report on Form 10-K, may be obtained without charge by contacting Longeveron at info@longeveron.com or visiting our website at www.longeveron.com.

ANNUAL MEETING - VIRTUAL

July 2, 2024 at 1:00 p.m. Eastern Time. Accessed through a live webcast at www.colonialstock.com/longeveron2024

TRANSFER AGENT

Colonial Stock Transfer
7840 S. 700 E.
SANDY UT 84070

INDEPENDENT AUDITORS

Marcum LLP, Accountants & Advisors
City Place I
185 Asylum Street, 25th Floor
Hartford, CT 06103

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

Factors that could cause actual results to differ materially from those expressed or implied in any forward-looking statements contained in this report include, but are not limited to, statements about our cash position and need to raise additional capital, the difficulties we may face in obtaining access to capital, and the dilutive impact it may have on our investors; our financial performance, ability to continue as a going concern and ability to remain listed on the Nasdaq Capital Market; 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 our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting; 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., Japan, The Bahamas, 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. You should not rely on these forward-looking statements as predictions of future events.