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, 2022

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 $18,000,000 as of June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter).

As of March 7, 2023, the registrant had 6,163,050 shares of Class A Common Stock, $0.001 par value per share, and 14,871,085 shares of Class B Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE. Part III of this Annual Report on Form 10-K incorporates certain information from the registrant's definitive proxy statement for its Annual Meeting of Stockholders to be held on June 2, 2023 (the "2023 Proxy Statement").

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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. Forward-looking statements contained in this 10-K include, but are not limited to, statements about:

- 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 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;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our need to raise additional capital, the difficulties we may face in obtaining access to capital, and the dilutive impact it may have on our investors;
- our financial performance; and
- 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.

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 report. 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.

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™ brand MSCs, an allogeneic medicinal signaling cell (MSC) therapy product isolated from the bone marrow of young, healthy adult donors. 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), Aging-related Frailty, and Alzheimer's disease (AD). Our mission is to advance Lomecel-B™ and other cell-based product candidates into pivotal Phase 3 trials, with the goal of achieving regulatory approvals, subsequent commercialization, and broad use by the healthcare community.

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 previously published Longeveron Phase 1 open-label study (ELPIS I)[1] 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.

Our philosophy is that healthy aging can be improved through regenerative medicine approaches. Life expectancy has substantially increased over the past century as a result of medical and public health advancements. However, this increase in longevity has not been paralleled by the number of years a person is expected to live in relatively good health, with limited chronic disease and disabilities of aging – a period known as healthspan. 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 declines. Our preliminary clinical data suggest that Lomecel-B™ can potentially address these problems through multiple mechanisms of action, or MOAs, that simultaneously target key aging-related processes.

Improving healthspan is an imperative for governmental health agencies. The National Institute on Aging (NIA), an institute of the National Institutes of Health (NIH), has promoted the concept of geroscience – the idea that aging itself is the biggest risk factor for aging-related human diseases and that aging can be approached as a treatable disease to improve healthspan. The geroscience hypothesis provides a strong rationale for the approach of treating underlying biological processes contributing to aging as a way to reduce disease burden and advance global human health. Our investments into developing and testing product candidates are aimed at reducing aging-related disease burden and improving healthspan.

Summary of Clinical Development Strategy

Our core strategy is to become a world-leading regenerative medicine company through the development 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.

- Focus on the execution of ELPIS II, a Phase 2 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 through grants from the NIH.

- Continue to develop our existing international programs. We have selected Japan as our first non-U.S. territory for a randomized, double-blinded, placebo-controlled clinical trial to evaluate Lomecel-B for Aging-related frailty with the aim of receiving approval under the Act on the Safety of Regenerative Medicine (ASRM) based on previous clinical data from non-Japanese as well as this Phase 2 study in Japan. We may explore conditional or full approval in Japan of Lomecel-B under the Pharmaceuticals and Medical Devices Act (PMDA) for the treatment of Aging-Related Frailty in the future. We may also explore other indications in Japan, and potentially pursue Aging-related frailty and other indications in additional international locations for further development and commercialization.

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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.

- Continue to pursue the therapeutic potential of Lomecel-B™ in Alzheimer's disease (AD). We have previously conducted a small Phase 1b study in which it appeared that a single dose of Lomecel-B™ may preserve cognition in patients with mild AD as compared to those who received placebo treatment. We are now conducting a small multiple-dose Phase 2 randomized placebo-controlled study in mild AD patients to determine the safety of administering up to four doses of Lomecel-B™ in this aged population. In addition to establishing safety for further investigation, we will endeavor to measure any positive effects of Lomecel-B™ in mild AD patients through a combination of cognitive and imaging endpoints as well as to determine the extent of target engagement by Lomecel-B™ in this patient population.

- 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 should Lomecel-B™ achieve 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 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 2023

We are currently in clinical development of a single product, Lomecel-B™ for three potential indications (See **Figure 1**).

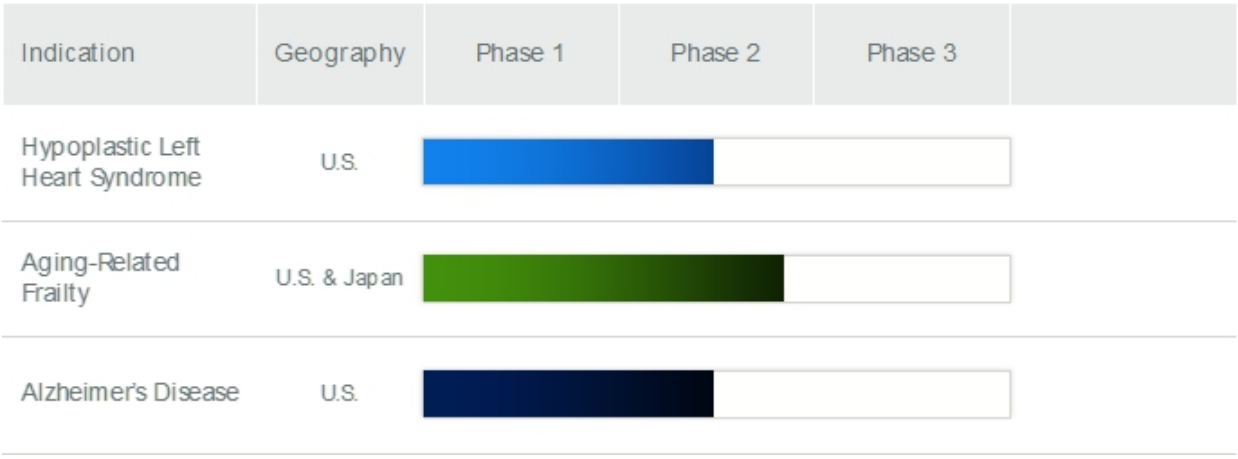

Figure 1: Lomecel-B™ clinical development pipeline

Hypoplastic Left Heart Syndrome (HLHS). Lomecel-B™ is being investigated in an ongoing Phase 2 clinical trial (ELPIS II) under FDA IND 017677. ELPIS II is a 38-subject, randomized, double-blind, controlled clinical trial designed to evaluate safety and efficacy of Lomecel-B™ in conjunction with reconstructive surgery compared to surgery alone. The trial is funded in part by the National Heart, Lung, and Blood Institute (NHLBI, part of the NIH). The trial is continuing to enroll patients in the study, and is being conducted as a investigator-initiated study led by Dr. Sunjay Kaushal through the auspices of the NHLBI at seven academic sites. This year it is anticipated that an eight site will be added to enhance the enrollment rate. We have not provided a projection for the date of completion of this study as enrollment to date has not been sufficient to provide such a projection.

Previously, we completed a Phase 1 study under FDA investigational new drug application (IND) 017677 to evaluate the safety, tolerability and preliminary evidence of Lomecel-B™ as a combinatorial therapy to surgery for this ultra-rare congenital heart defect. Babies born with this condition have an underdeveloped left ventricle and undergo a series of three surgeries to prevent certain death. Despite these life-saving surgeries, HLHS patients still have a high early mortality rate. We are investigating whether Lomecel-B™, directly injected into the heart during the second stage HLHS open-heart surgery, is safe and can improve short- and long-term outcomes in these vulnerable patients. These outcomes include heart function, and heart-transplant-free survival. The Phase 1 study met the primary safety endpoint: no major adverse cardiac events (MACE) nor any treatment-related infections during the first month post-treatment. In addition to the 12-month evaluation of outcomes from the original study, we have continued to follow these 10 patients, none of whom have required a heart transplant nor died from their cardiac disease for 3.4 to 5.0 years since the time of treatment with Lomecel-B. Of these patients, five have already undergone their stage III palliation surgery. Based on historical data, approximately 20% of patients who undergo stage II palliation surgery either require a heart transplant or die from HLHS within 12 months after their surgery. The apparent potential for a mortality benefit in HLHS paitents treated with Lomecel-B is the reason the FDA granted Rare Pediatric Disease (RPD) Designation and Orphan Drug Designation (ODD). Most recently, on August 24, 2022, the FDA granted Fast Track Designation for the potential treatment of HLHS with Lomecel-B™.

Aging-related Frailty. Aging-related Frailty is a life-threatening geriatric condition that disproportionately increases some patients' risk for poor clinical outcomes from disease and injury. It is believed by geriatricians to be treatable, although no approved pharmaceutical or biologic treatments currently exist for the condition. The definition of Aging-related Frailty lacks consensus and would be a new indication from a regulatory standpoint. As such, any approval of Lomecel-B™ for Aging-related Frailty will therefore require additional clinical data and continued discussion with the U.S. FDA and Japan's PMDA.

- We have previously completed two U.S. clinical trials under FDA IND 016644: (1) a multicenter, randomized, placebo-controlled Phase 2b trial ("Phase 2b Trial"), which showed that a single infusion of Lomecel-B™ improved 6-Minute Walk Test (6MWT) distance 9 months after infusion and also showed a dose-dependent increase in 6MWT distance 6 months after infusion; and (2) a multicenter, randomized, placebo-controlled Phase 1/2 trial ("HERA Trial") that showed that Lomecel-B™ was generally safe and well tolerated in this patient population. The results showed that hemagglutinin inhibition (HAI) responses in the Lomecel-B™™ and placebo groups to influenza were not statistically different.

- *Japan Clinical Trial*: The Japanese PMDA has approved a Clinical Trial Notification (CTN), which is equivalent to a U.S. IND, allowing an Investigator-sponsored Phase 2 clinical study for Aging-related frailty patients in Japan. This study is a 45-patient randomized placebo-controlled study with a primary objective of evaluating the safety of Lomecel-B™ in Japanese patients with Aging-related Frailty. The trial sites began screening patients at the end of 2022 and the first patient is expected to receive Lomecel-B in the first quarter of 2023. The goal of this study is to enable ASRM approval when combined with previous clinical results in non-Japanese patients.

- *The Bahamas Registry Trial*: We sponsor and operate a Registry Trial in Nassau, The Bahamas, where participants may receive Lomecel-B™ for Aging-related frailty and other indications, at the participant's own expense. Lomecel-B™ is designated as an investigational product in The Bahamas.

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, FL, which supplies Lomecel-B™ for our clinical trials and also serves as our corporate headquarters. We have and will continue to devote 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. We also intend to expand the manufacturing capacities in the U.S. and potentially Japan or other regions in Asia for commercialization at both a regional and global scale upon regulatory approvals.

Our 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 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. 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 21 CFR 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 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 Vista Health Research. 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, 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 will 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 in accordance with applicable federal and state 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 1,300 worldwide as of the first half of 2022.

In some of our indications, we face competition from both cellular therapy companies, and pharmaceutical/biotechnology companies. In our most important indication, Hypoplastic Left Heart Syndrome, we were unable to find a competing company currently addressing the condition. 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
Corestem	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
Pluristem Therapeutics, 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.

Biology of Aging Research Companies

To our knowledge, there are no other companies currently conducting clinical trials for Aging-related frailty using a regenerative medicine approach. However, this is likely to change as the emphasis on developing an effective treatment grows. Per ClinicalTrials.gov, as of February, 2023, there are a few groups testing different types of MSCs for frailty. This is not an exhaustive list; moreover, only "applicable clinical trials" under U.S. law are required to be listed in ClinicalTrials.gov:

- Healion Medical Inc. are recruiting subjects in the US to determine the safety and efficacy of delivery of autologous cellular stromal vascular fraction (cSVF) to improve the quality of life and functional health for patients with frail elderly syndrome.

- The Foundation for Orthopedics and Regenerative Medicine, Antigua and Barbuda are recruiting subjects to evaluate the safety of cultured allogeneic adult umbilical cord derived mesenchymal stem cell intravenous infusion for Aging-related frailty;

- Shanghai East Hospital in Shanghai, China is recruiting subjects for a multicenter, randomized, double-blind, placebo-controlled Phase 2 clinical study of umbilical cord MSC infusion for Aging-related frailty; and

- Vinmec Research Institute of Stem Cell and Gene Technology is planning to initiate a trial to investigate the safety and potential therapeutic efficacy of allogeneic administration of umbilical cord-derived MSCs (UC-MSCs) in combination with standard frailty treatment in Vietnam.

The University of Texas Health Science Center in San Antonio is collaborating with the NIH to conduct a randomized, placebo-controlled Phase 2 clinical trial of metformin, the Type-2 diabetes medication, for the prevention of frailty in subjects aged 65 to 95. Other academic groups or hospitals have or are testing hormonal treatments such as ghrelin or testosterone to prevent or treat frailty. Most interventional trials typically involve lifestyle intervention, specifically evaluating diet, dietary supplements, or exercise modifications, or a combination thereof. Several companies are researching different approaches and therapeutics in the broad "anti-aging" category, developing therapies that may extend "healthspan" by slowing or reversing diseases associated with aging, or the aging process itself.

- ***Calico Life Sciences, LLC***: This Google-backed company is researching compounds that are intended to treat aging-related diseases and conditions; however, its first clinical study involves patients with advanced solid tumor cancers.

- ***Unity Biotechnology*****:** Unity's focus is to "extend human health span, the period in one's life unburdened by the disease of aging." UBX is targeting senescence (the process whereby cells cease to divide, and linger in the body releasing harmful proteins) and is in the category called "senolytic medicines".

- ***AgeX Therapeutics***: AgeX is a pre-clinical stage company testing telomerase-expressing Pluripotent Stem Cells (PSCs) in an attempt to reverse cell aging and extend human health and life spans.

Competition in Alzheimer's Disease

There are several companies currently testing cellular therapy in neurologic and cognitive disorders. However, in the U.S., we believe we are the furthest advanced in the clinical development of a regenerative medicine approach to treating AD. The following companies have publicly indicated that they are conducting, or intend to conduct, cell therapy clinical trials in AD (does not include studies that were withdrawn). In addition, there are some academic groups (not listed) also exploring the potential therapeutic effects of MSCs in AD.

- ***Brainstorm Cell Therapeutics:*** In 2020, Brainstorm Cell Therapeutics, a U.S. company, announced its intention to initiate a multinational Phase 2 trial to test its autologous MSC neurotrophic factor investigational product in AD.

- ***VTBIO Co. LTD:*** VTBIO Co. LTD, a South Korean company, has reported that it has completed a Phase 2a study in AD using its umbilical cord-derived allogeneic MSCs. No results have been posted.

- ***MD Stem Cells:*** MD Stem Cells, a U.S. company, is enrolling by invitation a study entitled "Alzheimer's Autism and Cognitive Impairment Stem Cell Treatment Study" using what is described as "Intravenous Bone Marrow Stem Cell (BMSC) Fraction".

- ***Medipost Co. Ltd.:*** Medipost, a South Korean company, has reported that they are recruiting 12 patients for a trial testing the "Possibility of Using Regulatory T Cells (VT301) for Treatment of Alzheimer's Disease.

- ***NKGen Biotech, Inc:*** NKGen Biotech, a U.S. company, is recruiting a study of SNK01, a natural killer cell product, in a Phase 1 study to explore the safety, tolerability and efficacy in mild AD patients.

- ***Nature Cell Co. LTD:*** Nature Cell Co. LTD, a South Korean company, has reported completing a "Study to Evaluate the Safety and Efficacy of AstroStem [autologous adipose-derived MSCs] in Treatment of Alzheimer's Disease" in 21 patients. There are no references to any resulting publication.

- ***CHABiotech Ltd.:*** This South Korea-based company is conducting a Phase 1/2 trial of CB-AC-02, some kind of Mesenchymal Stem Cell. Based on the website of the company, these are enhanced placenta-derived stem cells in AD.

There are many other pharmaceutical and biotechnology companies that are conducting clinical trials of various therapeutics for the treatment of AD. According to the Alzheimer's Association, in 2021 there were 121 unique therapies registered on ClinicalTrials.gov. Some of the more established and well-known companies in this group include Biogen, Novartis, Eisai, and Eli Lilly.

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.

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 issue 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

*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 mesenchymal stem cell 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, 12 patent applications outside of the U.S. (in 12 jurisdictions), and a patent registration 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 one pending U.S. patent application, 12 patent applications outside of the U.S. (in 12 jurisdictions) and a patent registration 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 June 15, 2018 and claiming priority to a U.S. provisional application filed in June 2017. 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 Australia, Canada, China, the European Patent Organization, Hong Kong, Israel, Japan, South Korea, New Zealand, Singapore, South Africa, and the U.S. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in June 2038.

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 hypoplastic left heart syndrome with allogeneic mesenchymal stem cells. 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, if any, that are based on the PCT application must be filed as early as January 2024.

Administration of Mesenchymal Stem Cells for Aging-related frailty. This patent family relates to administration of mesenchymal stem cells for Aging-related frailty. In this family we own pending applications in Taiwan, the Bahamas, and the PCT. These applications share a common priority date of September 2021. National and regional phase applications, if any, that are based on the PCT application must be filed as early as March 2024.

Treatment of Alzheimer's Disease with Allogeneic Mesenchymal Stem Cells. We own one PCT patent application and an application in the Bahamas related to treatment of AD with allogeneic mesenchymal stem cells. Those applications were filed in September 2021 and claim priority to three separate U.S. provisional applications, the earliest of which was filed in September 2020. National phase applications, if any, that are related to the PCT application are not required to be filed until March 2023 at the earliest.

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 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 SOPs 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 $140,000 to UM, and as of December 31, 2022, we had accrued $50,000 in milestone fees payable to UM and $100,000 for patent related reimbursements based on the estimated progress to date.

JMH MD Holdings

On December 22, 2016, we entered into a worldwide exclusive license agreement with JMH MD Holdings ("JMHMD"), an affiliate of our Chief Science Officer, for the use of CD271+ technology, a subpopulation of bone marrow-derived MSCs. We are required to pay JMHMD a running royalty in an amount equal to one percent of the annual net sales of the licensed product(s) used, leased, or sold by or for us by any sub-licensees, 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, 2022 and 2021, 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, China, Israel, Japan, South Korea, Mexico, New Zealand, Germany, Spain, France, the United Kingdom, Italy, Sweden, and Singapore. The patent application remains pending in U.S. (where there are two pending utility applications), Canada, and Brazil. The Canadian and Brazilian applications have both been allowed. One of the U.S. applications is currently under appeal with the USPTO. 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	Pending
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 will work with 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, FDA may disagree with us, in which case we will follow 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 orphan drug designation (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 of "filing" to review and act on the submission. 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 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. 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 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.

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. 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, 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 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 FDA so that 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, 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 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. FDA may grant an orphan drug designation (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, 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 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 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 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 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 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. For fiscal year 2023, the application fee for a new drug or biologic requiring clinical studies is $3,242,026.

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 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

Under the 2014 law passed by the Japanese government, two new Acts were added that regulate regenerative medicine development and offer two pathways to market for regenerative medicine therapeutic candidates: The ASRM and the PMDA.

Japan's Act on the Safety of Regenerative Medicine. The ASRM route is intended to allow 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 ASRM route may require a clinical trial or other clinical data in order to seek approval from the MHLW. Treatments under the ASRM route must be provided by a medical institution for the purpose of either "medical research" or as a "medical treatment at one's own expense." Therapies provided under this framework are not covered by Japan's National Health Insurance.

Japan's Pharmaceutical & Medical Device Act. 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. A conditional approval can therefore occur after a Phase 2 trial. The conditional approval period lasts for a maximum of seven years. Sponsors that receive conditional approval must re-apply, with additional satisfactory safety and efficacy data, for a full unconditional approval within the timeframe provided to them under the conditional approval. A conditional approval allows the product to be marketed and partially reimbursed through Japan's National Health Insurance.

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 manufactures 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 physician utilization.

Payors are also increasingly reducing reimbursements for pharmaceutical products and services through continued implementation of cost-containment programs, including price controls, 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 for 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 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 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.

With these Congressional changes came continued yet unsuccessful attempts to repeal the ACA in its entirety through the judiciary. For example, on December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA were invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. There were also three separate challenges in front of the U.S. Supreme Court, the latest on June 17, 2021, wherein a challenge to the ACA from 18 Republican state attorneys general and the Trump Administration was rejected and dismissed for lack of standing.

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 Beilina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, 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, 2022, we had 19 full-time employees, two part-time employees and one full-time and one part-time consultant. Among those, five had M.D. or Ph.D. degrees, one has an M.A. degree, and one has a J.D. degree. Of these full-time employees and consultants, 14 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.

Information about our Executive Officers and other key employees is to be included in our 2023 Proxy Statement under the sections entitled "Executive Compensation," "Non-Employee Director Compensation," "The Board of Directors and its Committees—Compensation Committee Interlocks and Insider Participation" and is incorporated herein by reference.

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 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 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 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 Form 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, liquidity and capital challenges;
- The novelty of our technologies, whether their potential will be realized, and challenges in obtaining regulatory acceptance;
- Risks relating to the materials used in our products, and our processing and storage facilities;
- Future competition for product sales;
- We face risks related to the current COVID-19 pandemic and other health epidemics and outbreaks;
- We face risks, including inflation and supply shortages, resulting from adverse macroeconomic conditions resulting from various factors; 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 products and uses, others could compete against us more directly;
- If certain license agreements are terminated, our ability to continue clinical trials and commercially market products could be adversely affected;
- We may be unable to sufficiently protect the confidentiality of our proprietary information, trade secrets, and know-how;
- Third-party claims of intellectual property infringement may prevent or delay our product development efforts;
- If the Company's intellectual property has not all been properly assigned to the Company, we may not be able to commercialize our technology and derive revenue;
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage; and
- The potential impact of intellectual property regulation, legislation and litigation on our ability to operate.

Risks Related to Regulatory Approval and Other Governmental Regulations

- We may not be able to successfully develop our product candidates;
- Failure to get required regulatory approvals for conducting clinical trials, or final marketing approval;
- We may not be able to secure and retain research institutions to conduct our clinical trials; and
- Producing and marketing an approved drug or other medical product is subject to significant and costly post-approval regulation.

Risks Related to Our Dependence on Third Parties

- We face various risks relating to our reliance on third party suppliers, manufacturers and distributors;
- The successful commercialization of our current or future product candidates will depend on obtaining reimbursement from government and third-party payors;
- 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; and
- 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.

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 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, and our later stage or subsequent clinical trial results may not show efficacy, and may not support our earlier stage clinical safety and efficacy results for any particular indication that we are studying or may study;
- 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; and
- 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.

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

- We face volatility for various reasons with respect to our Class A Common Stock;
- We may be unable to access additional required capital, or be unable to access additional capital on terms that we find acceptable, and may be limited in the amount of capital we may raise due to our size;
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us;
- We are subject to securities litigation, which is expensive and could divert management attention; and
- 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 21 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 Hypoplastic Left Heart Syndrome 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, neither "Aging-related frailty" does not have a definition that are 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.

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 will depend on our Phase 2 clinical data and subsequent interactions with FDA where we would discuss the size and scope of a Phase 3 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. 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 the University of Miami (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 Alzheimer's disease, 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.

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, 2022, we had $19.7 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 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, 2022 and 2021, had an accumulated deficit of approximately $62.8 million and $43.9 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 64 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 involve 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.

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. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is 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.

Risks Related to Our Dependence on Third Parties

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.

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.

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 are 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 we recently 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. 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. In Japan, the PMDA is requiring us to conduct our Japanese Phase 2 trial in a Japanese population in order to demonstrate safety and efficacy in Japanese subjects. 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, 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, 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, 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 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 FDA. 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.

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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively 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.

Inadequate funding for the FDA and other government agencies, future government shutdown or furlough of government employees, or public health emergencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being reviewed or approved 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, the availability of industry-paid user fees, and statutory, regulatory, and policy changes. Average review times for product approvals at the FDA have fluctuated in recent years as a result. In addition, government funding of 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, including those resulting from the ongoing COVID-19 global pandemic, may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, if a prolonged government shutdown and/or government employee furloughs were to occur, or if FDA's response to a global pandemic such as COVID-19 diverts FDA resources and attention to other regulatory efforts, then the ability of the FDA to timely review and process our regulatory submissions, or inspect our or others' manufacturing facilities, could be significantly impacted, which could have a material adverse effect on our business, financial condition, and results of operations. Further, in our operations as a public company, future government shutdowns, furloughs or public health emergencies 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.

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 stock has been, and may continue to be, volatile, and you could lose all or part of your investment.

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;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- 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.

Our ability to raise capital in the future may be limited.

To date, our principal sources of capital used to fund our programs and other operations have been grant funding and the net proceeds we received from sales of equity securities. We have and will continue to use significant capital for the development and commercialization of our product candidates, and, as such, we expect to seek additional capital from future issuance(s) of our securities, which may consist of issuances of equity and/or debt securities, to fund our planned operations. Additional financing may not be available on favorable terms or at all. If adequate funds are not available on acceptable terms, we may be unable to fund our capital requirements. Because our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings. Thus, you bear the risk of our future securities offerings reducing the market price of our common stock and diluting your interest.

In December 2021, we raised approximately $20.5 million in gross proceeds through the sale of our equity securities under a Form S-1 registration statement. As of February 14, 2022, we are eligible to sell equity securities under a Form S-3 "shelf" registration statement. Using a shelf registration statement to raise capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, under current SEC rules and regulations, we must meet certain requirements to use a Form S-3 registration statement to raise capital without restriction as to the amount of the market value of securities sold thereunder. One such requirement is that we periodically evaluate the market value of our outstanding shares of common stock held by non-affiliates, or public float, and if, at an evaluation date, our public float is less than $75.0 million, then the aggregate market value of securities sold by us or on our behalf under the Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. Our public float is currently approximately $21.0 million and therefore we are currently subject to the one-third of our public float limitation. If our ability to use our Form S-3 shelf registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act of 1933 or under a Form S-1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to using our Form S-3 shelf registration statement.

Our ability to timely raise sufficient additional capital also may be limited by Nasdaq's stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock in an offering other than a public offering (as defined in Nasdaq listing rules). For instance, generally, stockholder approval is required prior to the issuance or potential issuance of common stock (or securities convertible into or exercisable for common stock) which (together with sales by our officers, directors and substantial shareholders (as defined in Nasdaq listing rules)) equals 20% or more of our common stock outstanding before the issuance at a price that is less than the lower of the closing price of our common stock or the five trading day average closing price of our common stock, in each case, immediately preceding the signing of the binding agreement (the "Minimum Price"). A public offering under Nasdaq rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing the company's stock price. Accordingly, the price at which we could sell our securities in a public offering may be less, and the dilution existing stockholders experience may in turn be greater, than if we were able to raise capital through other means.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

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 financings, 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Any such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business.

In addition, we currently have warrants issued that are subject to downward exercise price adjustments that may be triggered in a future financing, and which, if exercised, would also result in dilution. 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.

Information available in public media that is published by third parties, including blogs, articles, message boards and social and other media may include statements not attributable to the Company and may not be reliable or accurate.

We are aware of a large volume of information being disseminated by third parties relating to our operations, including in blogs, message boards and social and other media. Such information as reported by third parties may not be accurate, may lead to significant volatility in our securities and may ultimately result in our common stock or other securities declining in value.

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. In addition, the public stock markets have experienced extreme price and trading volume volatility. This volatility has significantly affected the market prices of securities of many companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our Class A Common Stock.

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

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

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

The trading market for our Class A Common Stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports 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 stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such approved products;
- regulatory developments affecting our product candidates or future products, or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our Class A Common Stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Holders of our Class B Common Stock will control the direction of our business and their ownership of our common stock will prevent other stockholders from influencing significant decisions.

As of December 31, 2022, two holders of our Class B Common Stock, consisting of two holders, own approximately 92% of the combined voting power of our Class A 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 you of an opportunity to receive a premium for your 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 we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A Common Stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Substandard internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years following our IPO. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements, require us to incur the expense of remediation, and result in a decline in the trading price of our stock.

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this 10-K;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in this 10-K and our periodic reports and proxy statements;
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved; and
- An extended transition period for complying with new or revised financial accounting standards.

We cannot predict if investors will find our Class A Common Stock less attractive because we may rely on these exemptions. If some investors find our Class A Common Stock less attractive as a result, there may be a less active trading market for our Class A Common Stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our IPO.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards and, therefore, our financial statements may not be comparable to other public companies that comply with public company effective dates. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations results in legal and financial compliance costs, makes some activities more difficult, time consuming or costly and increases demand on our systems and resources, including management. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These rules and regulations make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

We are subject to securities litigation, which is expensive and could divert management attention.

The market price of our Class A Common Stock may be volatile, and such volatility has made, and may continue to make, us subject to securities class action litigation. We have been the target of this type of litigation to date, and may also be in the future. Additional securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We do not currently intend to pay dividends on our Class A Common Stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our Class A Common Stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our Class A Common Stock, which is not certain.

Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A Common Stock.

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our Class A Common Stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

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

In addition, Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, 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.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the U.S. will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware;
- any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our certificate of incorporation further provides that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. If a court were to find these exclusive-forum provisions in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Nothing in our certificate of incorporation precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

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 the 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.

Item 1B. Unresolved Staff Comments

None.

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 3 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 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 seeks damages on behalf of a proposed class of purchasers of our Common Stock during said period. The Company entered into an agreement in principle with the plaintiffs to settle the litigation for $1.4 million. The settlement agreement is subject to final approval by the Court, which we expect to occur sometime in 2023. This amount is recorded as Non-operating Lawsuit expenses. Legal expenses incurred in ordinary business activities are reported within general and administrative expenses.

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 common stock is traded on The Nasdaq Capital Market under the under the symbol "LGVN."

Holders of Common Stock

As of March 7, 2023, there were 12 and 13 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, 6,147,481 shares of our Class A Common Stock and 14,891,085 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

None.

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), Aging-related Frailty, and Alzheimer's disease (AD). Our mission is to advance Lomecel-B and other cell-based product candidates into pivotal Phase 3 trials, with the goal of achieving regulatory approvals, subsequent commercialization, and broad use by the healthcare community.

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 March 7, 2023, we have completed four U.S. clinical studies of Lomecel-B: Phase 1 AD, Phase 1 HLHS, Phase 1/2 Aging-related frailty ("HERA Trial") and Phase 2b Aging-related frailty. We currently have three clinical trials actively enrolling patients: Phase 2a HLHS ("ELPIS II" trial), Phase 2a AD and Japan Phase 2 study in Japanese patients with Aging-related frailty. Additionally, we sponsor a registry in The Bahamas under the approval and authority of the National Stem Cell Ethics Committee. The Bahamas Registry Trial administers Lomecel-B to eligible participants at two 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 4,079,288 shares of Class A Common Stock through our IPO and a December 2021 private issuance of public equity (PIPE) offering, and warrants to purchase 1,169,288 shares of Class A Common Stock at an initial exercise price of $17.50 per share, for aggregate gross proceeds of $49.6 million prior to discounts, commissions and other offering expenses.

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 ($11.9 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 Trial. 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 expense" 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 ("UM"), 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: 1. those activities that should be identified as research and development; 2. the elements of costs that should be identified with research and development activities, and the accounting for these costs; and 3. the financial statement disclosures related to them. Research and development include costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, 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 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 increase 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 increase in the future as we increase our headcount to support increased administrative activities as a public company. We also expect to continue to incur expenses associated with being 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 short-term investments. We expect our interest income to increase due to the current cash and short-term investment 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

As of December 31, 2022, we are treated as a C corporation for federal and state income tax purposes. Prior to February 12, 2021, we were treated as a partnership for federal and state income tax purposes, whereby we passed our earnings and losses through to our members based on the terms of our Operating Agreement. No provision for income taxes has been recorded for the years ended December 31, 2022, and 2021. 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, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021, together with the changes in those items in dollars (in thousands):

	Year Ended December 31,		Increase
	2022	2021	(Decrease)
Revenues	$ 1,222	$ 1,306	$ (84)
Cost of revenues	725	716	9
Gross profit	497	590	(93)
Operating Expenses			
General and administrative	8,119	9,740	(1,621)
Research and development	9,370	7,092	2,278
Selling and marketing	1,051	1,214	(163)
Total operating expenses	18,540	18,046	494
Loss from operations	(18,043)	(17,456)	(587)
Other (expenses) and income			
Lawsuit expense	(1,398)	-	(1,398)
Forgiveness of Paycheck Protection Program loan	-	300	(300)
Interest expense	-	(4)	4
Other tax credits	306	58	248
Other income, net	300	57	243
Total other (expenses) and income, net	(792)	411	(1,203)
Net loss	$ (18,835)	$ (17,045)	$ (1,790)

Revenues, Cost of Revenues and Gross Profit: Revenues for the years ended December 31, 2022 and 2021 were $1.2 million and $1.3 million, respectively. The $0.1 million, or 6%, decrease when compared to 2021 was primarily due to a decrease in grant revenue year-over-year. Grant revenue for the year ended December 31, 2022 and 2021 was $0.3 million and $0.6 million, respectively. The decrease of $0.3 million, or 53% decrease when compared to 2021, 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 year ended December 31, 2022 and 2021 was $0.9 million and $0.7 million, respectively. Clinical trial revenue for the year ended December 31, 2022 increased by $0.2 million, or 33%, higher when compared to 2021 as a result of less COVID-19 travel restrictions, were less in 2022 as compared to 2021, and increased participant demand in the Bahamas Registry Trial in 2022.

Related cost of revenues was $0.7 million for the years ended December 31, 2022 and 2021. The less than $0.1 million, or 1%, increase when compared to 2021, was primarily due to more direct costs associated with our clinical trial revenue than our grants program. This resulted in a gross profit of approximately $0.5 million for the year ended December 31, 2022, a decrease of $0.1 million, or 16%, when compared with a gross profit of approximately $0.6 million for 2021.

General and Administrative Expense: General and administrative expenses for the year ended December 31, 2022 decreased to approximately $8.1 million, compared to $9.7 million for the same period in 2021. The decrease of approximately $1.6 million, or 17%, was primarily related to a decrease of $3.0 million in equity-based compensation expenses allocated to general and administrative expenses. However, employee benefit expenses increased by $0.5 million, which included a $0.4 million increase in expenses related to employee recruitment and insurance and professional fees increased by $0.2 million.

Research and Development Expenses: Research and development expenses for the year ended December 31, 2022 increased to approximately $9.4 million, from approximately $7.1 million for the same period in 2021. The increase of $2.3 million, or 32%, was primarily due to an increase of $2.6 million in research and development expenses that were not reimbursable by grants. The increase was offset by a decrease in equity-based compensation allocated to research and development expenses, which decreased from $2.2 million in 2021 to $1.1 million in 2022. 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,	
	2022	**2021**
Clinical trial expenses-statistics, monitoring, labs, sites, etc.	$ 4,170	$ 1,935
Supplies and costs to manufacture Lomecel-B™	817	504
Employee compensation and benefits	2,203	1,354
Equity-based compensation	1,096	2,228
Depreciation	681	720
Amortization	212	194
Travel	72	60
Other activities	119	97
Total	$ 9,370	$ 7,092

Selling and Marketing Expenses: Selling and marketing expenses for each of the years ended December 31, 2022 and 2021 was $1.0 million and $1.2 million, respectively. The decrease of $0.2 million, or 13%, was primarily due to a decrease in digital marketing expenses. Selling and marketing expenses consists primarily of investor and public relations expenses. Further and as disclosed in *Note 13. Reclassification of Prior Year Presentations*, during 2021, $0.9 million in expenses related to investor and public relations was recorded as general and administrative expenses and was reclassified as selling and marketing expenses as they were in 2022.

Non-operating Lawsuit expense: Non-operating Lawsuit expense for the year ended December 31, 2022 was approximately $1.4 million. This expense was deemed probable and therefore the amount was accrued in this period. 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.

Forgiveness of Paycheck Protection Program loan: Forgiveness of Paycheck Protection Program loan for the year ended December 31, 2022 was $0, compared to $0.3 million for the same period in 2021, due to the non-recurring nature of the forgiveness of the PPP loan.

Other tax credits: Other tax credits for each of the years ended December 31, 2022 and 2021 was $0.3 million and $0.1 million, respectively. Other tax credit increased 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 Income, net: Other income for the years ended December 31, 2022 and 2021 was $0.3 million and $0.1 million, respectively. Other income for 2022 increased as a result of an increase in realized returns from marketable securities of $0.2 million. Also recorded was approximately $27,000 for a gain resulting from foreign currency changes and $27,000 of sublease rental income. During 2021, $125,000 was received in rental payments recorded from a sublease, $60,000 from recorded investment income, $17,000 from a gain resulting from an equity exchange, $85,000 unrealized loss on marketable securities and $60,000 for a loss on disposal of equipment.

Net Loss: Net loss increased to approximately $18.8 million for the year ended December 31, 2022, from a net loss of $17.0 million for the same period in 2021. The increase in the net loss of $1.8 million, or 11%, 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,	
	2022	**2021**
Net cash used in operating activities	$ (13,969)	$ (9,636)
Net cash used in investing activities	(677)	(10,696)
Net cash (used in) provided by financing activities	(509)	45,174
Net (decrease) increase in cash and cash equivalents	$ (15,155)	$ 24,842

Operating Activities. We have incurred losses since inception. 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 as we incurred $1.4 million in non-operating lawsuit expenses, $2.3 million in equity-based compensation expenses and $0.9 million in depreciation and amortization expenses. Net cash used in operating activities for the year ended December 31, 2021 was $9.6 million, consisting primarily of our net loss of $17.0 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses, including an aggregate of $6.4 million of equity-based compensation recorded for RSUs and stock options granted and $1.3 million for non-cash stock payments to consultants.

Investing Activities. 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. Net cash used in investing activities for year ended December 31, 2021 was $10.7 million, consisting primarily of an increase of $9.4 million in marketable securities, recorded CRADA license agreement to intangibles of $0.8 million, and purchases of equipment of $0.3 million.

Financing Activities. 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. Net cash provided by financing activities for the year ended December 31, 2021 was $45.2 million consisting primarily of $26.7 million in net proceeds received from our IPO and $18.6 million in net proceeds received from the 2021 PIPE Offering.

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 increase 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, private placement equity financings, grant awards, and fees generated from the Bahamas Registry Trial and contract manufacturing services. Since we were formed, we have raised approximately $77.2 million in gross proceeds from the issuance of equity. As of December 31, 2022, the Company had cash and cash equivalents of $10.5 million, marketable securities of $9.2 million and working capital of approximately $15.4 million.

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, 2022, 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.

Grant Awards

From inception through December 31, 2022, 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, 2022, and 2021, the amount of unused grant funds that were available for us to draw was approximately $0.8 million and $1.4 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[4]	MSCRF - TEDCO	650,000	Ongoing
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 $0.2 million of the approximately $0.5 million apportioned to us.

(4) MSCRF - TEDCO has sent the first tranche of $325,000.

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 increase substantially 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, our expenses will increase as we:

- 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
- expand 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 through second half 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.

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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, 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, 2022, we have $3.0 million in operating lease obligations and $2.9 million in contract research organization 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, 2022 and 2021.

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 $19.7 million as of December 31, 2022. 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 on 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, 2022. 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 2023. 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, 2022, 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, 2022 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, 2022. 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, 2022, we maintained effective internal control over financial reporting.

Item 9B. Other Information

None.

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

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and incorporated by reference to our definitive Proxy Statement for our 2023 Annual Meeting of Shareholders, or our 2023 Proxy Statement, to be filed pursuant to Regulation 14A of the Exchange Act. If our 2022 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is to be included in our 2023 Proxy Statement as follows:

- The information relating to our directors and nominees for director is to be included in the section entitled "Proposal 1—Election of Directors;"
- The information relating to our executive officers is to be included in the section entitled "Executive Officers;"
- The information relating to our delinquent Section 16(a) reports, if any, is to be included in the section entitled "Delinquent Section 16(a) Reports;" and
- The information relating to our audit committee, audit committee financial expert and procedures by which shareholders may recommend nominees to our board of directors is to be included in the section entitled "The Board of Directors and its Committees."

We have adopted a written Code of Conduct and Ethics, or Ethics Code, that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Ethics Code is available on our website at www.horizontherapeutics.com. If we make any substantive amendments to the Ethics Code or grant any waiver from a provision of the Ethics Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website or in a Current Report on Form 8-K.

Item 11. Executive Compensation

The information required by this item is to be included in our 2023 Proxy Statement under the sections entitled "Executive Compensation," "Non-Employee Director Compensation," "The Board of Directors and its Committees—Compensation Committee Interlocks and Insider Participation" and "Compensation Discussion and Analysis" and is incorporated herein by reference.

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

The information required by this item with respect to equity compensation plans is to be included in our 2023 Proxy Statement under the section entitled "Equity Compensation Plan Information" and the information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our 2023 Proxy Statement under the section entitled "Other Information—Security Ownership of Certain Beneficial Owners and Management."

Item 13. Certain Relationships and Related Transactions and Director Independence

The following includes a summary of transactions as of December 31, 2022 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 transaction are the Company's related party transactions as of December 31, 2022:

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 Company agreed to issue the related party equity incentive units in the amount equal to 50% of the charges for invoiced services, with such equity to be issued annually on or about the anniversary date of the agreement. During 2017, the Company issued 1,901 Series C Units, and on November 22, 2019, and January 29, 2021, the Company issued 820 and 410 Series C Units, respectively, as payment for an aggregate of $0.2 million of accrued technology services. The Series C units were converted to 16,755 Class A common stock shares. As of December 31, 2022 and 2021, the Company owed less than $0.1 million, pursuant to this agreement, which is included in accounts payable in the December 31, 2022 and 2021 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 Series C Units as mutually agreed to by the parties. Amounts incurred amounted to approximately $126,000 and $10,000 during the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022, and 2021, 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 Chief Science Officer 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. There were no license fees due as of December 31, 2022 and 2021 pertaining to this agreement. 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, $17,000 and $42,000 for each of the years ended December 31, 2022 and 2021, in connection with the patent prosecution, issuance, and maintenance fees related to CD271+ technology.

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.

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 information required by this item with respect to principal accountant fees and services is to be included in our 2023 Proxy Statement under the section entitled "Principal Accountant Fees and Services" and the information required by this item with respect to fees and services is to be included in our 2023 Proxy Statement under the section entitled "Principal Accountant Fees and Services."

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. Incorporated by reference to Exhibit 4.2 of the Registrant's Annual Report on Form 10-K filed on March 11, 2022
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
10.1*	Exclusive License Agreement dated November 20, 2014 between the University of Miami and Longeveron LLC, incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.1.1	Amendment to Exclusive License Agreement dated December 11, 2017 between the University of Miami and Longeveron LLC, incorporated by reference to Exhibit 10.1.1 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.1.2	Second Amendment to Exclusive License Agreement dated March 3, 2021 between the University of Miami and Longeveron Inc., incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 9, 2021
10.2	Collaborative Research and Development Agreement dated March 3, 2021 between the University of Miami and Longeveron Inc., incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed March 9, 2021
10.3*	License Agreement dated December 22, 2016 between JMHMD Holdings, LLC and Longeveron LLC, incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021

10.3.1	First Amendment to License Agreement effective December 22, 2016, by and between JMHMD Holdings, LLC and Longeveron LLC, incorporated by reference to Exhibit 10.2.1 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.4#	Consulting Services Agreement, dated November 20, 2014, by and between Longeveron LLC and Joshua M. Hare, M.D., incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.5#	Employment Agreement, effective August 12, 2020 by and between Longeveron LLC and James Clavijo, incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement No. 333-252234 filed January 19, 2021
10.6*	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
10.10	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.
10.14#	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.
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, filed herewith
23.2	Consent of former Independent Registered Public Accounting Firm, filed herewith
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, filed 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, filed 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).

# 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).

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

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

Date: March 14, 2023

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 Hashasd Mohamed Wa'el Ahmed Hashad	Chief Executive Officer (principal executive officer)	March 14, 2023
/s/ James Clavijo James Clavijo	Chief Financial Officer (principal financial officer and principal accounting officer)	March 14, 2023
/s/ Joshua M. Hare Joshua M. Hare	Director	March 14, 2023
 Donald M. Soffer	Director	March 14, 2023
/s/ Neil E. Hare Neil E. Hare	Director	March 14, 2023
/s/ Rock Soffer Rock Soffer	Director	March 14, 2023
/s/ Douglas Losordo Douglas Losordo	Director	March 14, 2023
 Cathy Ross	Director	March 14, 2023
/s/ Erin Borger Erin Borger	Director	March 14, 2023
/s/ Ursula Ungaro Ursula Ungaro	Director	March 14, 2023
/s/ Todd C. Girolamo Todd C. Girolamo	Director	March 14, 2023

LONGEVERON, INC
FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Longeveron, Inc. (the "Company") as of December 31, 2022, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for the years ended December 31, 2022, 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, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

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

Hartford, CT
March 14, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Longeveron Inc (formerly known as Longeveron LLC) (the "Company") as of December 31, 2021, and the related statements of operations, members' and stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for each of the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

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 (U.S.) (PCAOB) and are required to be independent with respect to the Company in accordance with 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 a part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ MSL, P.A.

We have served as the Company's auditor since 2017.

Orlando, Florida
March 14, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 10,503	$ 25,658
Marketable securities	9,155	9,385
Prepaid expenses and other current assets	404	282
Accounts and grants receivable	218	55
Total current assets	20,280	35,380
Property and equipment, net	2,949	3,062
Intangible assets, net	2,409	2,334
Right-of-use (ROU) asset	1,531	1,813
Other assets	244	177
Total assets	$ 27,413	$ 42,766
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,751	$ 645
Accrued expenses	650	1,327
Current portion of lease liability	564	537
Estimated lawsuit liability	1,398	-
Deferred revenue	506	199
Total current liabilities	4,869	2,708
Long-term liabilities:		
Lease liability	2,041	2,605
Total long-term liabilities	2,041	2,605
Total liabilities	6,910	5,313
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share, 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and 2021	-	-
Class A Common Stock, $0.001 par value per share, 84,295,000 shares authorized, 6,127,320 shares issued and outstanding at December 31, 2022; 5,175,361 shares issued and outstanding at December 31, 2021	6	5
Class B Common Stock, $0.001 par value per share, 15,705,000 shares authorized, 14,891,085 shares issued and outstanding at December 31, 2022; 15,702,834 shares issued and outstanding at December 31, 2021	15	16
Additional paid-in capital	83,712	81,470
Stock subscription receivable	(100)	(100)
Accumulated deficit	(62,773)	(43,938)
Accumulated other comprehensive loss	(357)	-
Total stockholders' equity	20,503	37,453
Total liabilities and stockholders' equity	$ 27,413	$ 42,766

See notes to financial statements.

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

	Years ended December 31,	
	2022	**2021**
Revenues		
Grant revenue	$ 282	$ 598
Clinical trial revenue	940	708
Total revenues	1,222	1,306
Cost of revenues	725	716
Gross profit	497	590
Operating expenses		
General and administrative	8,119	9,740
Research and development	9,370	7,092
Selling and marketing	1,051	1,214
Total operating expenses	18,540	18,046
Loss from operations	(18,043)	(17,456)
Other (expenses) and income		
Lawsuit expense	(1,398)	-
Forgiveness of Paycheck Protection Program loan	-	300
Interest expense	-	(4)
Other refundable tax credits	306	58
Other income, net	300	57
Total other (expenses) and income, net	(792)	411
Net loss	$ (18,835)	$ (17,045)
Basic and diluted net loss per share	$ (0.90)	$ (0.90)
Basic and diluted weighted average common shares outstanding	20,969,032	18,915,086

See notes to financial statements.

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

	Years ended December 31,	
	2022	**2021**
Net loss	$ (18,835)	$ (17,045)
Other comprehensive loss:		
Net unrealized losses on available-for-sale securities	$ (357)	$ -
Total comprehensive loss	$ (18,478)	$ (17,045)

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		Member Units						
	Number	Amount	Number	Amount	Number of Units	Amount	Subscription Receivable	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholder's Equity
Balance at December 31, 2020	-	$ -	-	$ -	2,062,764	$ 2,057	$ (100)	$ -	$ -	$ -	$ 1,957
Conversion of Units into Class A and B common stock	338,030	-	15,702,834	16	(2,062,764)	(2,057)	-	28,934	(26,893)	-	-
Initial public offering and overallotment of Class A Common Stock, net of $2,969 in issuance costs	2,910,000	3	-	-	-	-	-	26,131	-	-	26,134
PIPE offering of Class A Common Stock, net of $1,968	1,169,288	1	-	-	-	-	-	18,494	-	-	18,495
Class A Common Stock, issued for RSUs vested	657,066	1	-	-	-	-	-	-	-	-	1
Class A Common Stock, held for taxes on RSUs vested	(123,662)	-	-	-	-	-	-	(452)	-	-	(452)
Class A Common Stock, issued for warrant exercises	51,061	-	-	-	-	-	-	613	-	-	613
Class A Common Stock, issued for stock option exercises	1,812	-	-	-	-	-	-	10	-	-	10
Class A Common Stock, issued for consulting	171,766	-	-	-	-	-	-	1,297	-	-	1,297
Equity-based compensation	-	-	-	-	-	-	-	6,443	-	-	6,443
Net loss	-	-	-	-	-	-	-	-	(17,045)	-	(17,045)
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, issued for stock option exercises	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 investments	-	-	-	-	-	-	-	-	-	(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

See notes to financial statements.

Longeveron Inc.
Statements of Cash Flows
(In thousands)

	Years ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (18,835)	$ (17,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	893	914
Forgiveness of Paycheck Protection Program loan	-	(300)
Loss on sale of equipment	-	60
Change in fair value of marketable securities	-	85
Equity issued to employees and consultants	170	1,297
Equity-based compensation	2,167	6,443
Non-operating lawsuit expense	1,398	-
Changes in operating assets and liabilities:		
Accounts and grants receivable	(164)	366
Prepaid expenses and other current assets	(122)	(227)
Other assets	(15)	(4)
Accounts payable	1,106	(945)
Deferred revenue	307	188
Accrued expenses	(677)	(214)
ROU asset and lease liability	(197)	(254)
Net cash used in operating activities	(13,969)	(9,636)
Cash flows from investing activities		
Marketable securities	179	(9,471)
Acquisition of intangible assets	(287)	(980)
Acquisition of property and equipment	(569)	(330)
Proceeds from sale of equipment	-	85
Net cash used in investing activities	(677)	(10,696)
Cash flows from financing activities		
Proceeds from initial public offering of common stock, net of commissions and expenses	-	26,695
Proceeds from secondary offering	-	18,495
Proceeds from warrants exercised	-	613
Proceeds from stock options exercised	2	10
Repayments of short-term note payable	-	(38)
Repayments of EIDL loan	-	(150)
Payments for Consulting fees with RSUs	(207)	-
Payments for taxes on RSUs vested	(304)	(451)
Net cash (used) provided by financing activities	(509)	45,174
(Decrease) Increase in cash and cash equivalents	(15,155)	24,842
Cash and cash equivalents at beginning of the period	25,658	816
Cash and cash equivalents at end of the period	$ 10,503	$ 25,658
Supplement Disclosure of Non-cash Investing and Financing Activities:		
Conversion of Series A, B and C units into Class A and B common stock	$ -	$ (2,057)
Vesting of RSUs into Class A Common Stock	$ -	$ (2,398)
Increase in deferred offering costs included in accounts payable and accrued expenses	$ -	$ 171

See notes to financial statements.

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

Nature of business:

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" or "we," "us," or "our"). 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. 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.

Initial Public Offering ("IPO"):

On February 12, 2021 our Class A Common Stock, par value $0.001 per share (the "Class A Common Stock") began to trade on NASDAQ under the stock symbol "LGVN". Pursuant to the IPO, the Company sold 2,660,000 shares of Class A Common Stock at a public offering price of $10.00 per share for aggregate gross proceeds of $26.6 million prior to deducting underwriting discounts, commissions, and other offering expenses. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 399,000 shares at the public offering price less the underwriting discounts and commissions.

On March 15, 2021, the Company's underwriters partially exercised the over-allotment option, resulting in the Company selling an additional 250,000 shares of Class A Common Stock at a public offering price of $10.00 per share for aggregate gross proceeds of $2.5 million prior to deducting underwriting discounts, commissions, and other offering expenses.

Private Placement

On December 3, 2021, the Company completed a private placement with several investors, wherein a total of 1,169,288 shares of the Company's Class A Common Stock were issued at a purchase price of $17.50 per share, with each investor also receiving a warrant 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"), for a total purchase price of approximately $20.5 million (the "2021 PIPE Offering"). 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 therein. 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.

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.

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 Trial 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 $18.8 million and $17.0 million for the years ended December 31, 2022 and 2021, respectively. In addition, as of December 31, 2022, the Company had an accumulated deficit of $62.8 million. The Company expects to continue to generate operating losses for the foreseeable future.

As of December 31, 2022, the Company had cash, and cash equivalents of $10.5 million and marketable securities of $9.2 million. The Company believes that its cash and cash equivalents and investments as of December 31, 2022 will enable it to fund its operating expenses and capital expenditure requirements through at least the next 12 months from the date of issuance of these financial statements.

2. Summary of Significant Accounting Policies

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

In December 2019, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2019-12, "Income Taxes (Topic 740)". The amendments in this ASU simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and by clarifying and amending other areas of Topic 740. The amendments in this ASU are effective for annual and interim periods beginning after December 15, 2020. We adopted this ASU on January 1, 2021 with no material impact on our financial statements.

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.

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, 2022 and 2021 consisted of marketable fixed income securities, primarily corporate bonds, as well as U.S. Government and agency obligations which are categorized as trading securities and are thus marked to market and stated at fair value in accordance with 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. In addition, under ASC 320 *Investments in Debt and Equity Securities*, the investments are to be categorized into one of three categories at acquisition: (1) held-to-maturity; (2) available-for-sale; and (3) trading. Initially our assessment was that these instruments were considered trading securities; however, based upon our current cash needs, we now believe that these should be appropriately categorized as available-for-sale securities. 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 as accumulated other comprehensive income (loss) in the Statement of stockholders' equity during 2022. Changes in net unrealized gains and losses were not significant for the year ended December 31, 2021.

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, 2022 and 2021, 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, 2022 and 2021 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.

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

	December 31,	
	2022	**2021**
National Institutes of Health – Grant	$ 218	$ 55
Total	$ 218	$ 55

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. During 2021, offering costs incurred in connection with the 2021 PIPE Offering of approximately $0.2 million were netted against the proceeds from the private placement. Offering costs of $0.6 million have been prepaid as of December 31, 2020 and then netted against the IPO proceeds as of December 31, 2021.

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 as of December 31, 2022 and 2021.

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, 2022 and 2021, the Company recognized $0.1 million and $0, 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,	
	2022	2021
National Institute of Health - grant	$ 164	$ 212
Clinical trial revenue	940	708
Alzheimer's Association grant	-	260
MSCRF – TEDCO[1] - grant	118	126
Contract manufacturing revenue	-	-
Total	$ 1,222	$ 1,306

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. ASC 730 addresses the proper accounting and reporting for research and development costs. It identifies: 1) those activities that should be identified as research and development; 2) the elements of costs that should be identified with research and development activities, and the accounting for these costs; and 3) the financial statement disclosures related to them. Research and development costs include costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, property and equipment depreciation and allocation of various corporate costs. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, patient enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

Concentrations of credit risk:

Financial instruments which potentially subject the Company to credit risk consist principally of cash and cash equivalents, marketable securities and accounts and grants receivable. Cash and cash equivalents are held in U.S. financial institutions. At times, the Company may maintain balances in excess of the federally insured amounts.

Income taxes:

Prior to its Corporate Conversion, the Company was treated as a partnership for U.S. federal and state income tax purposes. Consequently, the Company passed its earnings and losses through to its members based on the terms of the Company's Operating Agreement. Accordingly, no provision for income taxes is recorded in the financial statements for periods prior to the conversion.

Following the Corporate Conversion, 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 year ended December 31, 2022 and 2021 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, 2022 and 2021, 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 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:

	Fair Value at December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. Treasury obligations	96,981	-	-	96,981
U.S. government agencies	-	1,250,003	-	1,250,003
Corporate and foreign bonds	-	7,807,655	-	7,807,655
Money market funds[(1)]	607,262	-	-	607,262
Accrued income	64,815	-	-	64,815
Total marketable securities	$ 769,059	$ 9,057,658	$ -	$ 9,826,717

	Fair Value at December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. Treasury obligations	401,290	-	-	401,290
U.S. government agencies	-	1,424,477	-	1,424,477
Corporate and foreign bonds	-	7,507,705	-	7,507,705
Money market funds[(1)]	576,742	-	-	576,742
Accrued income	52,484	-	-	52,484
Total marketable securities	$ 1,030,516	$ 8,932,182	$ -	$ 9,962,698

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

As of December 31, 2021 our assessment of the above marketable securities was that these instruments were considered trading securities; however, based upon our current cash needs, we now believe that these should be categorized as available-for-sale securities as of December 31, 2022. As of December 31, 2022 and 2021, the Company reported accrued interest receivable related to marketable securities of $64,815 and $52,484, respectively. 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, 2022, the Company recorded unrealized losses attributable to changes in marketable securities of $357,334. These unrealized losses were recorded on the Balance sheet as accumulated other comprehensive loss.

As of December 31, 2022 and 2021, the amortized cost of these securities was $9,428,000 and $9,471,000, respectively.

4. Property and equipment, net

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

	Useful Lives	December 31, 2022	December 31, 2021
Leasehold improvements	10 years	$ 4,328	$ 4,318
Furniture/Lab equipment	7 years	2,264	1,724
Computer equipment	5 years	46	28
Software/Website	3 years	38	38
Total property and equipment		6,676	6,108
Less accumulated depreciation and amortization		3,727	3,046
Property and equipment, net		$ 2,949	$ 3,062

Depreciation and amortization expense amounted to approximately $0.7 for the years ended December 31, 2022 and 2021.

5. Intangible assets, net

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

Major components of intangible assets as of December 31, 2021, are as follows (in thousands):

	Useful Lives	Cost	Accumulated Amortization	Total
License agreements	20 years	$ **2,043**	$ (473)	$ 1,570
Patent Costs		**615**	-	615
Trademark costs		**149**	-	149
Total		**$ 2,807**	$ (473)	$ 2,334

Amortization expense related to intangible assets amounted to approximately $0.2 million for the years ended December 31, 2022 and 2021.

Future amortization expense for intangible assets as of December 31, 2022 is approximately as follows (in thousands):

Year Ending December 31,	Amount
2023	$ 224
2024	224
2025	224
2026	89
2027	62
Thereafter	535
Total	$ 1,358

6. Leases

The Company records a Right-of-use (ROU) 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, 2022, the ROU asset and lease liability were approximately $1.5 million and $2.6 million, respectively. As of December 31, 2021, the ROU asset and lease liability were approximately $1.8 million and $3.1 million, respectively.

Future minimum payments under the operating leases as of December 31, 2022 are as follows (in thousands):

Year Ending December 31,	Amount
2023	$ 687
2024	702
2025	719
2026	735
2027	184
Total	3,027
Less: Interest (5% discount rate)	422
Present Value of Lease Liability	$ 2,605

During each of the years ended December 31, 2022 and 2021, the Company incurred approximately $1.0 million 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. As compared to the year ended December 31, 2021, where $102,500 was recognized as sublease income and is included in other income in the accompanying statements of operations.

7. Members' Equity and Stockholders' Equity

IPO

The Corporate Conversion undertaken immediately prior to the Company's IPO caused all existing Series A and B units to convert into Class B Common Stock and all existing Series C units to convert into Class A Common Stock. The purpose of the Corporate Conversion was to reorganize the Company structure so that the entity that offered the Company's Class A Common Stock to the public was a Delaware corporation rather than a Delaware limited liability company, and so that the Company's existing investors own the Company's Class A Common Stock or Class B Common Stock rather than equity interests in a limited liability company.

On February 12, 2021 our Class A Common Stock, par value $0.001 per share (the "Class A Common Stock") began to trade on NASDAQ under the stock symbol "LGVN". Pursuant to the IPO, the Company sold 2,660,000 shares of Class A Common Stock at a public offering price of $10.00 per share for aggregate gross proceeds of $26.6 million prior to deducting underwriting discounts, commissions, and other offering expenses. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 399,000 shares at the public offering price less the underwriting discounts and commissions.

On March 15, 2021, the Company's underwriters partially exercised the over-allotment option, resulting in the Company selling an additional 250,000 shares of Class A Common Stock at a public offering price of $10.00 per share for aggregate gross proceeds of $2.5 million prior to deducting underwriting discounts, commissions, and other offering expenses.

2021 PIPE Offering

On December 3, 2021, the Company completed the 2021 PIPE Offering wherein a total of 1,169,288 shares of the Company's Class A Common Stock were issued at a purchase price of $17.50 per share, with each investor also receiving a warrant 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 2021 PIPE Offering, at an exercise price of $17.50 per share (the "Purchaser Warrants"), for a total purchase price of approximately $20.5 million (the "Offering"). 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 therein. 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.

Class A Common Stock

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 October 3, 2022, a total of 20,157 RSUs granted in connection with the Company's IPO vested, of which 18,001 were held by Company employees. Based on the closing price of $3.75 on October 3, 2022, the Company recorded a tax liability of $16,000 for the employees and a corresponding tax liability for the Company of $2,000. In total, the Company paid $18,000 for employee and employer taxes that resulted from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 4,204 shares of Class A Common Stock owned by the Company's employees upon vesting. The shares withheld are available for reissuance pursuant to the 2021 Incentive Plan.

On July 1, 2022, a total of 20,158 RSUs granted in connection with the Company's IPO vested, of which 18,002 were held by Company employees. Based on the closing price of $5.94 on July 1, 2022, the Company recorded a tax liability of $26,000 for the employees and a corresponding tax liability for the Company of $2,000. In total, the Company paid $28,000 for employee and employer taxes that resulted from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 4,726 shares of Class A Common Stock owned by the Company's employees upon vesting. The shares withheld are available for reissuance pursuant to the 2021 Incentive Plan.

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 June 3, 2022, a total of 26,666 RSUs that previously had been granted to our Chief Financial Officer and General Counsel vested. 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 ($8.73 on June 3, 2022) and a tax liability is calculated based on each individual's tax bracket. As a result, on June 3, 2022, the Company recorded a tax liability of $55,000 for the employees and a corresponding tax liability for the Company of $2,000. In total, the Company paid $57,000 for employee and employer taxes resulting from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 6,254 shares of Class A Common Stock owned by the Company's employees upon vesting. The shares withheld are available for reissuance pursuant to the 2021 Incentive Plan.

On April 4, 2022, a total of 1,167 RSUs that previously had been granted to our Chief Medical Officer vested. Based on the closing price of $12.85 on April 3, 2022, the Company recorded a tax liability of $5,000 for the employee and a corresponding tax liability for the Company of $1,000. In total, the Company paid $6,000 for employee and employer taxes that resulted from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 357 shares of Class A Common Stock owned by the Chief Medical Officer upon vesting. The shares withheld are available for reissuance pursuant to the 2021 Incentive Plan.

On April 1, 2022, a total of 31,016 RSUs granted in connection with the Company's IPO vested, of which 26,360 were held by Company employees. Based on the closing price of $15.61 on April 1, 2022, the Company recorded a tax liability of $105,000 for the employees and a corresponding tax liability for the Company of $14,000. In total, the Company paid $119,000 for employee and employer taxes that resulted from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 6,222 shares of Class A Common Stock owned by the Company's employees upon vesting. The shares withheld are available for reissuance pursuant to the 2021 Incentive Plan.

On April 1, 2022, a total of 2,500 RSUs vested that were previously granted to a member of the Company's Board of Directors vested.

On February 12, 2022, a total of 8,750 RSUs that were previously granted to members of the Company's Board of Directors upon the completion of the IPO vested.

On January 3, 2022, a total of 35,246 RSUs granted in connection with the Company's IPO vested, of which 29,614 were held by Company employees. Based on the closing price of $12.09 on January 3, 2022, the Company recorded a tax liability of $92,000 for the employees and a corresponding tax liability for the Company of $14,000. In total, the Company paid $106,000 for employee and employer taxes that resulted from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 10,627 shares of Class A Common Stock owned by the Company's employees upon vesting. The shares withheld are available for reissuance pursuant to the 2021 Incentive Plan.

During the year ended December 31, 2021, and prior to the Corporate Conversion, the Company issued 1,130 Series C Common Membership Units ("Series C Units"), as payment for existing consulting agreements, with an aggregate value of $0.1 million. As part of the Corporate Conversion, 62,764 outstanding Series C units (which includes the units referenced in the prior sentence) converted into 338,030 shares of Class A Common Stock.

Also, during the year ended December 31, 2021, the Company issued 61,379 and 110,387 unregistered shares of Class A Common Stock, with an aggregate value of less than $0.5 million and $0.8 million, respectively, as payment under consulting and license agreements.

During the year ended December 31, 2022, 374 stock options were exercised for Class A Common Stock shares at an average exercise price of $5.73 for $2,143.

During the year ended December 31, 2021, 1,812 stock options were exercised for Class A Common Stock shares at an average exercise price of $5.73 for $10,383. Also, during the year ended December 31, 2021, 51,061 warrants were exercised for Class A Common Stock shares at an exercise price of $12.00 for $612,732.

On October 1, 2021, a total of 35,256 RSUs granted to employees and directors vested, of which 33,022 were held by Company employees. Based on the closing price of $3.65 on October 1, 2021, the Company recorded a tax liability of $452,000 for the employees and a corresponding tax liability for the Company of $38,000. In total, the Company paid $489,000 for employee and employer taxes that resulted from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 123,662 Class A Common Stock shares owned by the Company's employees upon vesting. The shares withheld are available for reissuance pursuant to the 2021 Incentive Plan.

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, 2022, shareholders exchanged 811,749 shares of Class B Common Stock for 811,749 shares of Class A Common Stock.

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, 2021, 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 2021 PIPE Offering, the Company issued 1,169,288 warrants to investors 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.

Prior Period Members' Equity

	Series A Units		Series B Units		Series C Units	
	Number of Units	Amount	Number of Units	Amount	Number of Units	Amount
Balance at December 31, 2019	1,000,000	$ 250	1,000,000	$ 1,832	43,695	$ 2,513
Series C units issued for cash	-	-	-	-	18,335	1,100
Issuance of Series C units as payment for amounts accrued	-	-	-	-	734	44
Equity-based compensation	-	-	-	-	-	39
Balance at December 31, 2020	1,000,000	$ 250	1,000,000	$ (1,777)	62,764	$ 3,584

	Series A Units		Series B Units		Series C Units	
	Number of Units	Amount	Number of Units	Amount	Number of Units	Amount
Balance at December 31, 2020	1,000,000	$ 250	1,000,000	$ (1,777)	62,764	$ 3,584
Conversion of Units into Class A and B common stock	(1,000,000)	(250)	(1,000,000)	1,777	(62,764)	(3,584)
Balance at December 31, 2021	-	$ -	-	$ -	-	$ -

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 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 September 6, 2022, the Company granted Mr. Bailey an equity incentive award of 20,000 RSUs. The RSUs will 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 will be subject to Mr. Bailey's continued service through the applicable vesting dates. RSUs shall be expensed on a quarterly basis at the rate of $5,838 for the quarterly vesting amount of 1,250 RSUs, with a price per share of $4.67 (the closing price of the Company's stock on September 6, 2022).

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.

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 provides for annual base salary of $350,000, and he will be 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 will 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 will be subject to Dr. Min's continued service through the applicable vesting dates. RSUs shall be 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 shall be 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 July 20, 2021, the Company granted a bonus for the completion of the IPO to Mr. Green, Mr. Lehr and Dr. Hare of $100,000, $75,000 and $75,000, respectively. The bonus was paid out in cash and RSUs with Mr. Green, Mr. Lehr and Dr. Hare receiving 8,223, 6,167 and 12,335 RSUs each, respectively. The RSU were issued based on a fair market value at the time of grant, July 20, 2021, of $6.08.

As of December 31, 2022 and 2021, the Company had 329,746 and 196,751, respectively RSUs outstanding (unvested).

RSU activity for the year ended December 31, 2022 was as follows:

	Number of RSUs
Outstanding at December 31, 2021	196,751
RSU granted	333,329
RSUs vested	(162,031)
RSU expired/forfeited	(38,304)
Outstanding (unvested) at December 31, 2022	329,746

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 have the following assumptions: 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 2022 and 2021, will be expensed ratably over the option vesting periods, which approximates the service period.

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. Also, as of December 31, 2021, the Company has recorded issued and outstanding options to purchase a total of 304,449 shares of Class A Common Stock pursuant to the 2021 Incentive Plan, at a weighted average exercise price of $5.96 per share.

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

For the year ended December 31, 2021:

	Number of Stock Options
Stock options vested (based on ratable vesting)	59,773
Stock options unvested	244,676
Total stock options outstanding at December 31, 2021	304,449

Stock Option activity for the year ended December 31, 2022 was as follows:

	Number of Stock Options	Weighted Average Exercise Price
Outstanding at December 31, 2021	304,449	$ 5.96
Options granted	242,003	$ 8.16
Options exercised	(374)	$ 5.73
Options expired/forfeited	(75,887)	$ 6.08
Outstanding at December 31, 2022	470,191	$ 7.07

On December 21, 2022, the Company granted an award of 5,000 Class A Common Stock options to each of its directors (a total of 45,000). 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 $135,000 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. Lehr. 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.

On April 22, 2021, the Company granted awards of 64,125 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 $5.73. Based upon a Black-Scholes calculation, the price per share to be expensed was $5.03 and a total cost of $0.3 million would be expensed ratably over 48 months.

On May 5, 2021, 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 $5.89. Based upon a Black-Scholes calculation, the price per share to be expensed was $5.17 and a total cost of less than $0.1 million would be expensed ratably over 48 months.

On May 17, 2021, the Company granted an award of 30,000 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 $5.29. Based upon a Black-Scholes calculation, the price per share to be expensed was $4.64 and a total cost of approximately $0.1 million would be expensed ratably over 48 months.

On June 1, 2021, the Company granted an award of 5,000 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 $6.77. Based upon a Black-Scholes calculation, the price per share to be expensed was $5.94 and a total cost of less than $0.1 million would be expensed ratably over 48 months.

On July 20, 2021, the Company granted 225,000 Class A Common Stock options to executives. Mr. Green was granted 75,000 Class A Common Stock options and Mr. Lehr, Dr. Hare and Mr. Clavijo were each granted 50,000 Class A Common Stock options. The stock options have four-year vesting periods, vesting 12.5% on July 22, 2021 with the remaining award vesting in equal installments over the remaining four years, with an exercise price of $6.08. Based upon a Black-Scholes calculation, the price per share to be expensed was $5.32 and a total cost of $1.2 million would be expensed ratably over 48 months.

For the years ended December 31, 2022 and 2021, the equity-based compensation expense amounted to approximately $2.3 million and $6.4 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, 2022 and 2021.

As of December 31, 2022, the remaining unrecognized equity-based compensation (which includes RSUs and stock options) of approximately $2.9 million will be recognized over approximately a weighted average of 4.0 years.

9. Commitments and Contingencies

Master Services and Clinical Studies Agreements:

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. The Company expects these agreements or amended current agreements to have total expenditures of approximately $2.9 million over the next two years. On March 10, 2022, the Company entered into a clinical studies agreement with a third party in conjunction with an upcoming clinical trial in Japan. The agreement provides for payments totaling $1.0 million over the course of two years.

As of December 31, 2021, 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. As of December 31, 2022, the Company had an accrued balance due to the CSO of approximately $22,000 and as of December 31, 2021 had a balance due of $164,000.

Technology Services Agreement:

On March 27, 2015, the Company entered into a technology services agreement with Optimal Networks, Inc. (a related company owned by a Dr. Joshua Hare's brother-in-law) for use of information technology services. The Company agreed to issue the related party equity incentive units in the amount equal to 50% of the charges for invoiced services, with such equity to be issued annually on or about the anniversary date of the agreement. During 2017, the Company issued 1,901 Series C Units, and on November 22, 2019, and January 29, 2021, the Company issued 820 and 410 Series C Units, respectively, as payment for an aggregate of $0.2 million of accrued technology services. The Series C units were converted to 16,755 Class A common stock shares. As of December 31, 2022 and 2021, the Company owed less than $0.1 million, pursuant to this agreement, which is included in accounts payable in the December 31, 2022 and 2021 balance sheets.

Exclusive Licensing Agreements:

UM Agreement

On November 20, 2014, the Company entered into an Exclusive License Agreement with UM for the use of certain Aging-related frailty-related MSC technology rights developed by our Chief Science Officer 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 IMSCs, all SOPs 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 HLHS 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 $140,000 to UM, and as of December 31, 2022, we had accrued $50,000 in milestone fees payable to UM and $100,000 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, 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, 2022 and 2021 pertaining to this agreement.

Other Royalty

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

Contingencies – Legal

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 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 seeks damages on behalf of a proposed class of purchasers of our Common Stock during said period. The Company entered into an agreement in principle with the plaintiffs to settle the litigation for $1.4 million. The settlement agreement is subject to final approval by the Court, which we expect to occur sometime in 2023. This amount is recorded as Non-operating Lawsuit expenses. Legal expenses incurred in ordinary business activities are reported within general and administrative expenses.

Contingencies – COVID-19 Pandemic

The Company continues to monitor new developments on how the COVID-19 pandemic is affecting the Company's employees, business, and clinical trials. During the initial stages associated with the spread of COVID-19, the Company instructed all employees who could perform their essential employment duties from home to do so. The Company's laboratory scientists, cell-processing scientists and other manufacturing personnel continued to work from its cGMP facility and headquarters on a day-to-day basis, and as such, cell production was minimally impacted. Certain other employees continue to maintain a fully remote or "hybrid" work arrangement as their roles allow. When the pandemic began to emerge in the U.S., most of the Company's ongoing clinical trials had completed enrollment. However, a few subjects that were on-study and in follow-up experienced difficulties in adhering to the protocol visit schedule. Because the Company primarily enrolls older adults in its trials, who are at particular risk for poor outcomes related to COVID-19 infection, the Company experienced some disruption in executing the follow-up visits in its studies. These disruptions resulted in challenges that included temporary clinical site closures, the inability to leave a residence due to regional "stay-at-home" orders and an unwillingness of trial subjects to leave their residence to visit the hospital or clinic. To minimize and mitigate these disruptions, the Company conducted remote visits (via telemedicine), arranged for in-home visits for phlebotomy in order to collect blood samples and other protocol-specific assessments, and amended protocols to increase the window of time for follow-up visits. Despite these efforts, several subjects missed follow-up visits, had their follow up visit outside of the protocol-defined time-window, or withdrew from the trial prior to completion. Regardless, given the steps implemented by Longeveron, the cumulative instances were few and did not appear to have a material impact on its now-completed Phase 2b Aging-related frailty study, Phase 1 Vaccine trial, Phase 1 Alzheimer's disease trial, and Phase 1 HLHS clinical trial.

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 have completed one year of service. Contributions to the Plan by the Company are at the discretion of the Board of Directors.

The Company contributed approximately $88,000 and $66,000 to the Plan during the years ended December 31, 2022 and 2021, 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, 2022 and December 31, 2021 (the Company did not have deferred tax assets or liabilities as of December 31, 2020 as it was just incorporated in 2021):

	2022	2021
Deferred tax assets:		
Net operating loss carry forwards	$ 6,103,000	$ 2,250,000
ASC842 Lease liability	690,000	3,142,000
Equity based compensation	1,993,000	1,641,000
Fixed assets	435,000	-
Intangible assets	45,000	-
Capitalized research & development expenses	1,753,000	-
Accrual to cash adjustment	911,000	240,000
Total deferred tax assets	11,930,000	7,273,000
Valuation allowance	(11,524,000)	(5,665,000)
Deferred tax assets, net of valuation allowance	406,000	1,608,000
Deferred tax liabilities:		
ASC842 Right-of-use asset	(406,000)	(1,813,000)
Changes in other assets	-	227,000
Depreciation and amortization	-	(22,000)
Total deferred tax liabilities	(406,000)	(1,608,000)
Deferred tax assets and liabilities, net of valuation allowance	$ -	$ -

As of December 31, 2022, the Company had NOL carryforwards for federal purposes of approximately $23 million, all of which have no expiration. The Company also had state NOL carryforwards of approximately $22.8 million, which expire at various dates through 2043. 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, 2022 and 2021 were as follows:

	2022	2021
Federal tax at statutory rate	21.0%	21.0%
State tax benefits, net of federal benefit	6.9	3.7
Other	0.8	3.0
Change in valuation allowance	(28.7)	(27.7)
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, 2022, 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, 2022 and 2021.

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,	
	2022	2021
RSUs	330	197
Stock options	470	304
Warrants	1,271	1,271
Total	2,071	1,772

13. Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations. An adjustment has been made to the Statement of Operations for the Years Ended December 31, 2021. During 2021, $1.0 million in expenses related to investor and public relations had been recorded as general and administrative expenses rather that in selling and marketing expenses. This change in classification does not affect previously reported operation expenses in the Statement of Operations.

14. Subsequent Events

On January 3, 2023, previously disclosed RSUs granted to employees and directors vested. A total of 20,161 RSUs vested of which 18,005 were held by Company employees. 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 $3.37 closing price as of the vesting date (January 3, 2022) and a tax liability is calculated based on each individual's tax bracket. As a result, on January 3, 2022, the Company recorded a tax liability of $15,000 for the employees and a corresponding tax liability for the Company of $2,000. In total, the Company paid $17,000 for employee and employer taxes that resulted from the vesting of RSUs. In order to cover the employee tax liability, the Company withheld 4,431 shares of Class A Common Stock owned by the Company's employees upon vesting. The shares received have been transferred into the 2021 Incentive Plan.

On February 22, 2023, the Board of Directors of Longeveron Inc. (the "Company") appointed Mr. Mohamed Wa'el Ahmed Hashad to serve as the Company's Chief Executive Officer, effective March 1, 2023. Mr. Hashad will also join the Company's Board of Directors at such time as such appointment may be accomplished without violating any requirements under Nasdaq. Dr. Chris Min, who has been serving as interim Chief Executive Officer, will continue to serve as Chief Medical Officer. In connection with his appointment as Chief Executive Officer, the Company and Mr. Hashad entered into a Letter Agreement effective as of March 1, 2023 (the "Agreement"). Under the terms of the Agreement, Mr. Hashad will receive 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 will receive a signing bonus of 50,000 Restricted Stock Units, which shall vest 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.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Longeveron Inc. on Forms S-1 [File Nos. 333-252234 and 333-261667], S-3 [File No. 333-264142] and S-8 [File No. 333-253141] of our report dated March 10, 2023, with respect to our audit of the financial statements of Longeveron Inc. as of December 31, 2022 and for the year ended December 31, 2022, which report is included in this Annual Report on Form 10-K of Longeveron Inc. for the year ended December 31, 2022.

/s/ Marcum LLP

Marcum LLP
Hartford, CT
March 14, 2023

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Longeveron Inc.
Miami, Florida

We hereby consent to the incorporation by reference in Registration Statements on Form S-1 (Nos. 333-252234 and 333-261667), Form S-3 (No. 333-264142), and Form S-8 (No. 333-253141) of Longeveron Inc. (the "Company") of our report dated March 11, 2022, relating to the financial statements of the Company as of December 31, 2021 and for the year ended December 31, 2021, which appears in this Annual Report on Form 10-K of the Company for the year ended December 31, 2022.

/s/ MSL, P.A.

Orlando, Florida
March 14, 2023

Exhibit 31.1

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

I, Wa'el Hashad, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 14, 2023

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

Exhibit 31.2

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

I, James Clavijo, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 14, 2023

/s/ James Clavijo
James Clavijo
Chief Financial Officer

Exhibit 32.1

SECTION 1350 CERTIFICATION

In connection with the Annual Report of Longeveron Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Wa'el Hashad, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: March 14, 2023

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

Exhibit 32.2

SECTION 1350 CERTIFICATION

In connection with the Annual Report of Longeveron Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Clavijo, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: March 14, 2023

/s/ James Clavijo
James Clavijo
Chief Financial Officer