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Brad Sorensen, CFA

312-265-9574

bsorensen@zacks.com

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Longeveron Inc

(LGVN-NASDAQ)

LGVN: A clinical stage biotech company using cellular technology to attempt to ease major medical issues.

LGVN is a clinical stage biotech company that is using cutting edge cellular technology to treat a rare heart disease and the impacts of aging. We place a \$20.00 valuation on LGVN using the discounted cash flow model.

OUTLOOK

Longeveron Inc. is using donated cells from living humans in an effort to find a way to create better outcomes for children suffering from Hypoplastic Left Heart Syndrome. The treatment, known as Lomecel-B, was granted Orphan Drug status by the FDA.

The company is also testing Lomecel-B in the treatment of the devastating effects of Alzheimer's Disease, while also attempting to dampen the impact of Aging Frailty, a condition impacting millions.

Current Price (01/25/22) **\$7.07**
Valuation **\$20.00**

SUMMARY DATA

52-Week High **\$42.30**
52-Week Low **\$2.92**
One-Year Return (%) **N/A**
Beta **N/A**
Average Daily Volume (sh) **1,793,066**

Shares Outstanding (mil) **20**
Market Capitalization (\$mil) **\$139**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **2**
Insider Ownership (%) **N/A**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
Sales (%) **N/A**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2022 Estimate **N/A**
P/E using 2023 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **High**
Type of Stock **Small-Growth**
Industry **Med-Biomed/Gene**
Zacks Rank in Industry **N/A**

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	0.3 A	0.5 A	0.2 A	0.2 E	1.2 E
2022	0.3 E	0.2 E	0.2 E	0.4 E	1.1 E
2023	0.3 E	0.4 E	0.4 E	0.3 E	1.4 E
2024	0.3 E	0.3 E	0.4 E	0.3 E	1.3 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-\$0.18 A	-\$0.26 A	-\$0.25 A	-\$0.25 E	-\$0.94 E
2022	-\$0.21 E	-\$0.23 E	-\$0.20 E	-\$0.10 E	-\$0.74 E
2023	-\$0.19 E	-\$0.20 E	-\$0.18 E	-\$0.17 E	-\$0.74 E
2024	-\$0.17 E	-\$0.19 E	-\$0.16 E	-\$0.22 E	-\$0.74 E

INITIATING COVERAGE

LONGEVERON™

CELL-BASED THERAPIES

We are initiating coverage of Longeveron Incorporated (LGVN) with a valuation of \$20.00. Longeveron is a Miami-based, clinical-stage biotechnology company focused on developing cellular therapies for chronic diseases associated with aging and other life-threatening conditions. Management at Longeveron believes that by using the same cells that promote tissue repair, organ maintenance and immune system function, the company can develop safe and effective therapies for some of the most difficult disorders associated with the aging process.

Longeveron's lead investigational candidate is a cellular therapy known as Lomecel-B, which is being evaluated in multiple clinical trials and life-threatening conditions under United States FDA-approved Investigational New Drug (IND) Applications. Although Longeveron's main focus is on age-related maladies, breakthroughs can be found through the research process in other areas as well.

In 2021, Lomecel-B was granted Rare Pediatric Disease (RPD) and the Orphan Drug Designation (ODD) by the FDA for the treatment of Hypoplastic Left Heart Syndrome (HLHS), which is a rare and life-threatening defect in infants. The ODD designation for the treatment of HLHS was the biggest development recently but research and trials for Lomecel-B are ongoing for such conditions as: Alzheimer's, Aging Frailty, Metabolic Syndrome and Acute Respiratory Distress Syndrome (ARDS).

Longeveron has no revenue from sales of products at this point in time and we project it will be several more years before commercialization of therapies currently under development comes to fruition. But, unlike many companies at this stage of development, Longeveron is not strapped for cash at this point. Due to the nature of their research, rare, tough to solve conditions, the company has been able to fund operations with grants from various governmental and non-profit organizations. Since inception through September 30, 2021, Longeveron has received approximately \$11.9 million in government and non-profit association grants. This method of funding increases the attractiveness of LGVN in our minds as there is likely to be less dilution for shareholders due the company not needing to go to the equity markets to continue to do business.

Longeveron did enter the equity world in a major way in early 2021 by participating in an Initial Public Offering for just over \$29 million by listing on the NASDAQ under the symbol LGVN, while also completing a private placement deal which netted just under \$20 million for the company. With the company's positive capital position and positive developments in recent trials that are detailed below, we believe that LGVN has to potential to be both a good, yet speculative, investment prospect for investors, and a potential acquisition target for major pharmaceutical companies looking to bolster their pipelines.

INVESTMENT CASE

Longeveron is a clinical-stage biotechnology company developing cellular therapies for age-related chronic diseases, while also attempting to address other life-threatening conditions. Longeveron operates with the central belief that the same cells in human bodies that promote healing and function, such as tissue repair, organ maintenance or immune system function, can be developed into therapies that are both safe, published research to date has demonstrated that allogeneic MSC administration has been well-tolerated, and effective at battling some of the most difficult disorders associated with the aging process.

Longeveron's lead investigational therapeutic candidate for achieving those goals is a cellular therapy that goes by the name of Lomecel-B, which, as noted above, is currently being evaluated in multiple clinical trials under the FDA's Investigational New Drug (IND) program. Per FDA.gov, current law requires that a drug, or in this case cellular therapy, be the subject of an approved marketing application before it can be transported or distributed across state lines. And because getting testing done, especially on rare diseases with limited patient populations to choose from, will likely require patients from multiple states, the FDA technically grants an exception to this law by using the IND program as long as it is shown that the product in question is reasonably safe for use in humans and if the compound "exhibits pharmacological activity that justifies commercial development.

Lomecel-B

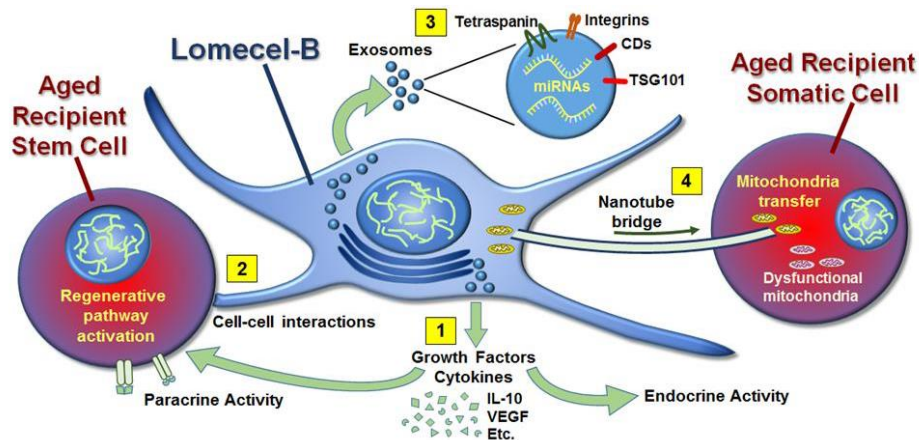
Before addressing the various conditions Longeveron is currently testing Lomecel-B for, we feel it's valuable to understand how the therapy works. Once the mechanisms of action of Lomecel-B are understood, at least somewhat, we believe that investors will be able to imagine what other uses this therapy might have in the future.

First, where does it come from? Lomecel-B is made from living cells called Medicinal Signaling Cells (MSCs) that are isolated from fresh bone marrow tissue donated by adult donors, alleviating some of the ethical concerns that can surround some forms of cell research and their sources. Once these MSCs are isolated, the cells are culture expanded (allowed to replicate under controlled laboratory conditions) into billions of living cells. After a specific number of expansion cycles, the cells are harvested and separated into specific doses. This method of harvesting and replicating cells has several inherent advantages, including:

- Cells harvested from living human donors have characteristics that allow them to be transplanted from donor to host without triggering a harmful immune response.
- Therapies using these cells can be administered on an out-patient basis in as little as 40 minutes after thawing.
- This has an advantage over a patient using their own cells and then reintroducing them back into the same person—which requires a surgical procedure and can take weeks or months and can only be used on one patient.
- Therapies using these cells are considered an "off-the-shelf" product, which means they are stored frozen and available for on-demand use.
- Data from clinical studies suggest the effects of a single dose may last over 6 months.
- The source for the starting raw material is young healthy adult donors.

Now that we know where it comes from, how does it work? Here it gets a bit more complicated but also makes some intuitive sense. Although the research is ongoing, the researchers at Longeveron currently believe that there are several mechanisms of action believed to mediate therapeutic benefits. First, there is the release of growth factors and other proteins, such as anti-inflammatory

cytokines, which are a type of protein that have an effect on the immune system. These cytokines have the potential to reduce inflammation and stimulate nearby stem cells to promote regenerative and repair responses. Further, the Lomecel-B cells engage in direct cell-to-cell interaction to induce positive pathways in contacted cells. Lomecel-B cells can also release exosomes, which are the functional part of the genome and carry RNA, proteins, and other molecules that can be taken up by other cells to provide beneficial effects and have the potential to form nanotube bridges, which can allow the exchange of mitochondria and other cellular contents between cells. For those that want a pictorial representation of the process:



Source: <https://www.longeveron.com/lomecel-b> December 9, 2021

Hypoplastic Left Heart Syndrome

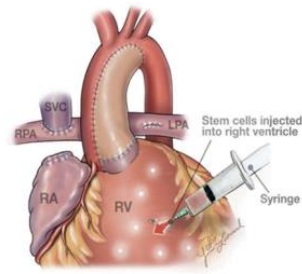
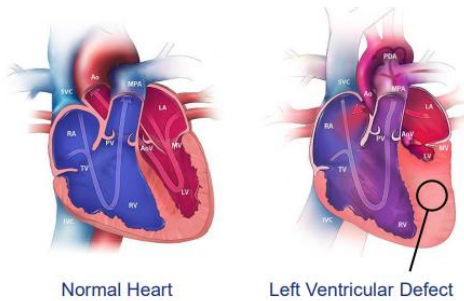
Now that we understand how Lomecel-B works, at least somewhat, now let's talk about where it's being studied for effectiveness. One of the most exciting developments has come recently with the granting of Lomecel-B with both Rare Pediatric Disease (RPD) and the Orphan Drug Designation (ODD) by the FDA in 2021 for the treatment of Hypoplastic Left Heart Syndrome (HLHS). The RPD award may come with a priority review voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product. That priority review can also be sold, as has happened with other companies, to other medical companies in the future. ODD is designed to support development and evaluation of new treatments for rare diseases and comes with benefits to the receiver of that designation of:

- Tax credits for qualified clinical trials.
- Exemption from user fees for the potential submission of a marketing application—currently valued at around \$2.9 million.
- Gives the receiving company the potential of seven years of market exclusivity after approval.

And HLHS certainly qualifies as it is a rare and life-threatening heart defect in infants. HLHS is a congenital birth defect estimated by the Center for Disease Control to impact 1,025 babies in the US every year, or the equivalent to 1 in every 3,841 babies born. HLHS describes a condition in which the left ventricle (picture below) is either severely underdeveloped or missing.

Having this condition leads to severely diminished blood flow and typically requires a complex, 3-stage heart reconstruction surgery process over the first five years of a child's life. Advances have been made and children with HLHS can now live into adulthood, but early mortality is still extremely high due to right ventricle failure, which can't handle the increase load demanded for systemic circulation.

Longeveron is aiming to improve those odds with an injection of Lomecel-B that the company theorizes will improve the outcomes of surgery.



Source: <https://www.longeveron.com>, December 9, 2021

Initial results from the Phase I trial, which was completed in 2021, were promising:

- The trial met the primary safety endpoint—there were no major cardiac events—nor were there any treatment-related infections during the first month post treatment.
- The therapy was delivered during Stage II surgery and 100% of infants treated (10) survived free of heart transplant.
- The follow up period ranged from 2-3.5 years after cardiac surgery
- These results contributed to the FDA granting Lomecel-B Rare Pediatric Disease Designation (RPD) in November 2021.
- As a result, Longeveron can be awarded priority review vouchers that can be redeemed to receive priority review of a subsequent marketing application.

The results from Phase I trials of Lomecel-B on the treatment of HLHS has led to the beginning of a Phase II trial. The Phase II trial will consist of 38 subjects that are being actively enrolled and will be randomized in a double-blind and controlled study. The study is designed to evaluate the efficacy of Lomecel-B in conjunction with reconstructive surgery compared to surgery alone. As mentioned above, much of Longeveron's funding comes from governmental sources and this is no different as the study is being funded by a grant from the National Institute of Health's National Heart, Lung and Blood Institute. The primary outcome measure will be the change in right ventricular ejection fraction at 12 months post treatment. There will be secondary endpoints as well:

- Changes in right ventricular function and morphology.
- Changes in growth.
- Change in clinical outcomes.
- Change in quality of life.
- Change in blood biomarkers.

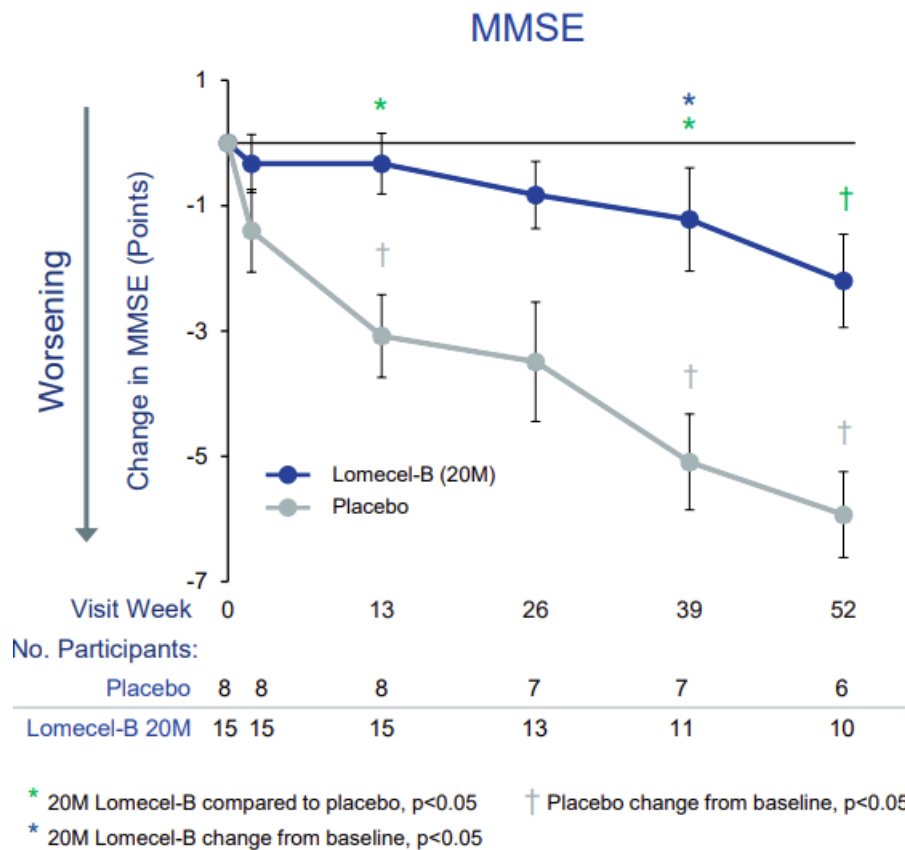
Results from Phase II will of course be crucial to the future of this treatment, and to the investment case of Longeveron, but HLHS is certainly not a condition associated with the aging process, which is the stated focus of the company and that's the category where the rest of the ongoing trials rest.

Alzheimer's Disease

One of the most feared aspects of aging among many is the prospect of not being able to recognize those who have been known for years nor remember crucial and beloved memories of a life lived—in short—the prospect of being diagnosed with Alzheimer's Disease. We don't need to go into too many details of the dreaded disease as most are all too familiar with it, but it is the most common cause of dementia, accounting for between 60-80% of cases and afflicting as many as 5.8 million Americans according to the CDC—projected to grow to 14 million by 2060. There is no cure and currently, according to the Alzheimer's Association, there is only one treatment—aducanumab (brand name Aduhelm produced by Biogen and Neurimmune)—which removed amyloid, one of the hallmarks of Alzheimer's Disease.

According to the CDC, Alzheimer’s Disease is the 6th leading cause of death among US adults and the 5th leading cause for adults aged 65 or older. And the costs to society are almost immeasurable in certain terms but in monetary terms, a paper by Winston Wong, who is a Scholar in Resident at the UCLA Kaiser Permanente Center for Health Equity, estimated the cost is 2020 at \$305 billion, and estimated by the CDC to growth to more than \$500 billion by 2040.

It is these tragic facts that Longeveron is attempting to mitigate with Lomecel-B. The company is testing Lomecel-B as a treatment for Alzheimer’s based on the hypothesis that multiple possible mechanisms of action (MOAs) can simultaneously address multiple features of Alzheimer’s. Preclinical studies show that MSCs (Medicinal Signaling Cells) can potentially reduce Alzheimer’s-associated brain inflammation, improve the function of blood vessels in the brain, and reduce brain damage due to Alzheimer’s Disease progression and promote regenerative responses. Longeveron has completed the Phase I safety study of subjects with mild Alzheimer’s disease and based on the success is intending to initiate a larger Phase II study. The Phase I trial was supported by a Part the Cloud grant from the Alzheimer’s Association, which could result in payments from the company to the Association should a therapy reach commercialization status. Based on the preliminary results—seen below in the form of measuring memory with a Mini Mental State Exam (MMSE)—Longeveron is hopeful Lomecel-B may prove to be a disease-modifying therapy for Alzheimer’s Disease.



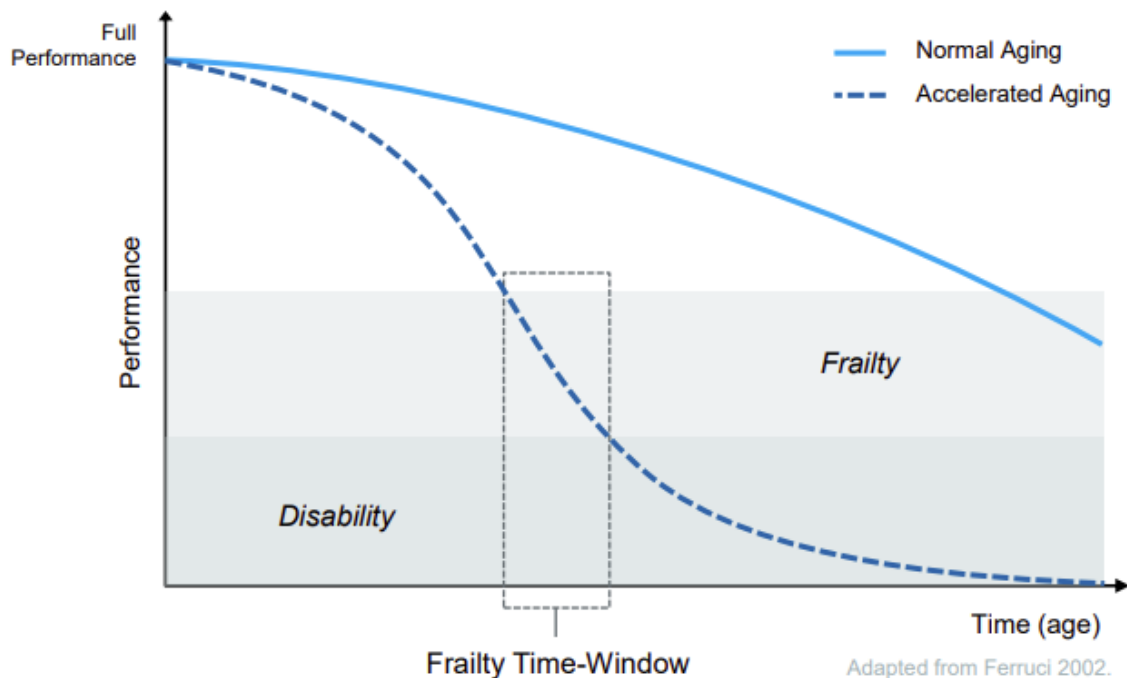
MMSE: Mini Mental State Exam; 20M: 20 million.

Source: <https://www.longeveron.com> December 9, 2021

Ageing Frailty Research Program

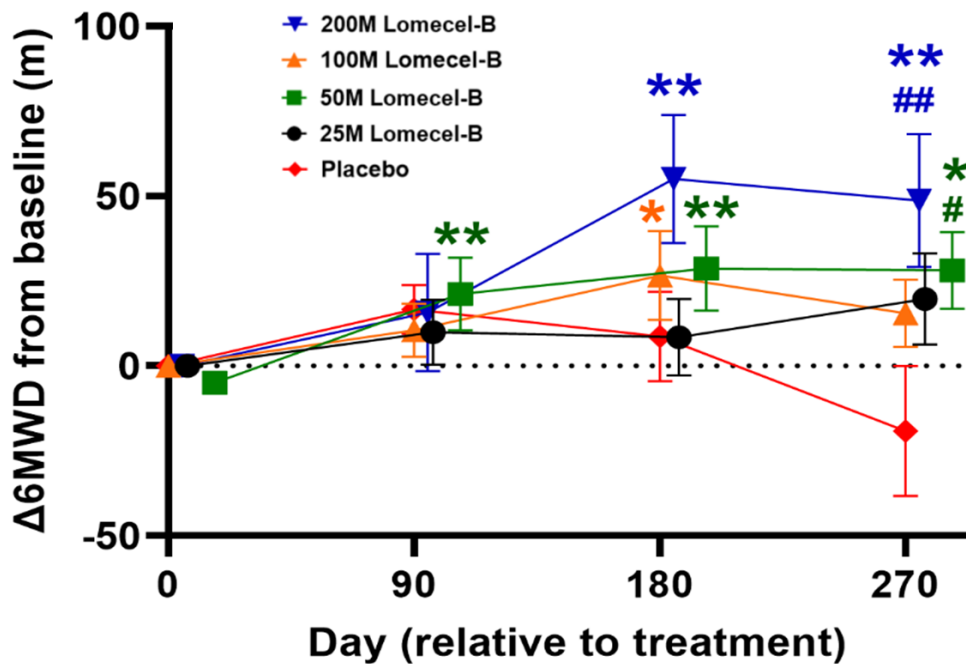
There are extreme events that can impact older people’s lives, such as Alzheimer’s, and then there are just the natural impacts of aging—can’t run as fast, get tired a little sooner, etc.—and then there

is a middle ground that is seldom talked about—Aging Frailty. Aging Frailty is a common geriatric condition that disproportionately increases a patient's risk for poor clinical outcomes due to disease and injury—in short, it accelerates and magnifies the aging process. Here's a picture of what it looks like in graphic form:



Source: <https://www.longeveron.com> December 9, 2021

And it's not an uncommon condition with various studies cited by Longeveron, including one from John Hopkins, suggesting that approximately 15% of individuals in the US above 65 years of age are impacted, which equates to roughly 8.1 million people. And of course, there are aging populations all over the world that are impacted by Aging Frailty, with Japan, for example, having 28% its total population aged 65 and above and approximately 7% of those estimated to have Aging Frailty. To this point, there are no medical treatments approved by the FDA or any other major countries' drug overseer, but Longeveron is not the only player pursuing treatment options for this cohort, with multiple competitors in the space at various places along the path toward commercialization. Longeveron is testing Lomecel-B for possible therapeutic use in Aging Frailty cases and announced the results from its Phase 2b research trial in August 2021, which was funded by a Small Business Administration Grant from the National Institute of Health's National Institute of Aging. The results showed a statistically significant difference at the 270 day mark in terms of the change in 6-minute walk test (6MWT), which is a standard, low risk test used to assess aerobic activity and endurance and was the primary endpoint of the study. (The primary efficacy endpoint was change in 6MWT at day 180 for Lomecel-B cohorts compared to placebo cohort. This time point did not reach statistical significance of a p-value <0.05, however it did at day 270)

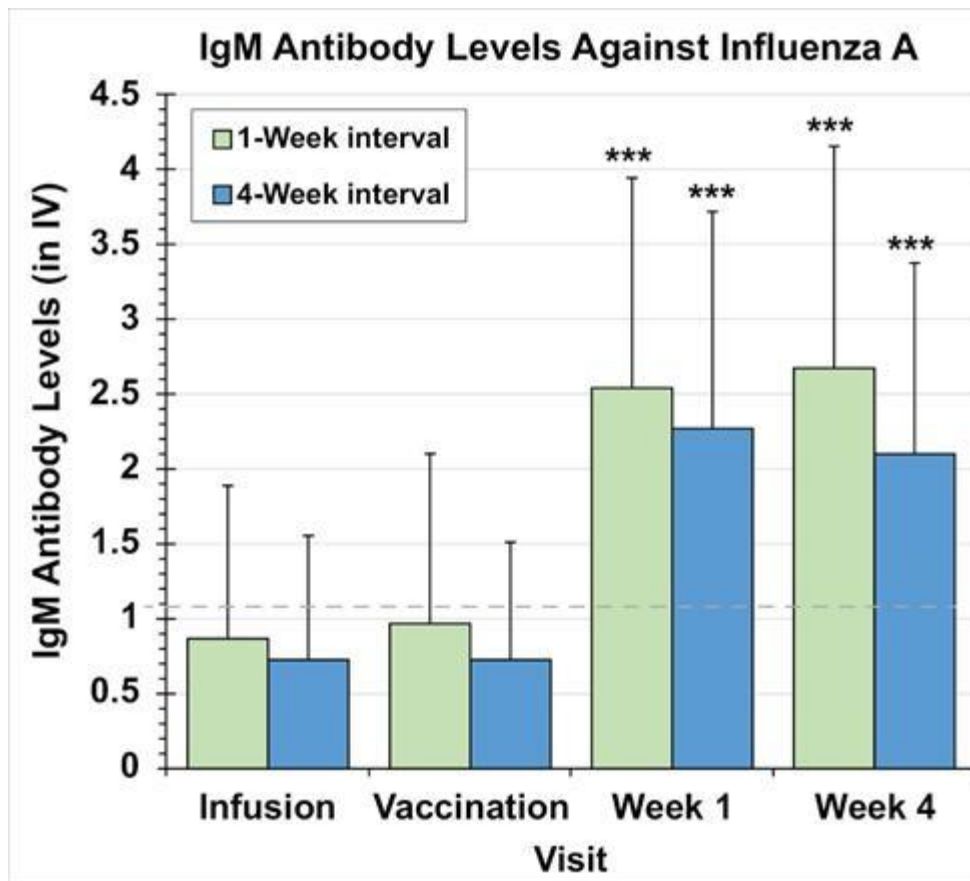


* Change from baseline; p<0.05 # Versus placebo; p<0.05
 ** Change from baseline; p<0.01 ## Versus placebo; p<0.01

Source: <https://www.longeveron.com>, January 21, 2021

However, secondary analysis showed no statistically significant difference compared to the placebo with regard to patient questionnaire PROMIS, which involves physical function, or serum level of tumor necrosis alpha, which is an inflammatory cytokine. But Longeveron was approved for a Clinical Trial Notification in Japan, similar to the IND approval by the FDA in the US, by the Japanese Pharmaceuticals and Medicals Division. This approval allows Longeveron to sponsor an investigator-initiated Phase 2 clinical study for Aging Frailty subjects in Japan, which should give us more insight into the potential viability of Lomecel-B in combating Aging Frailty. Additional trials have been ongoing in the Bahamas since 2017, where Longeveron has a sponsored registry, which allows the company to administer Lomecel-B treatment to eligible participants at two private clinics in Nassau. Lomecel-B is considered an investigational product in The Bahamas and, as such, Longeveron is permitted to charge a fee to participate in the program and we'll be watching for results from that ongoing trial in the future.

As part of its battle against Aging Frailty, Longeveron, in 2Q 2021, announced the completion of an exploratory trial of the impact of Lomecel-B on the administration of the flu vaccine to those with Aging Frailty. Aging Frailty is associated with decreased immune response, which increases the importance of vaccines, but the weakened immune system means that this group often has trouble responding positively to such immunizations as the flu vaccine. The initial results appeared positive as a positive antibody response occurred in all patients treated with Lomecel-B—shown below.



Longeveron is also another malady associated with Aging Frailty and the potential impact Lomecel-B may be able to have on it. The Metabolic Syndrome Research program, which is sub-study of the Aging Frailty program to evaluate if Lomecel-B may improve the symptoms of Metabolic Syndrome. Metabolic Syndrome has no approved therapies at this point and develops over years to decades and leads to cardiovascular disease and Type II diabetes mellitus. The condition is described by a cluster of conditions, including high blood pressure, high blood sugar, excess body fat and abnormal cholesterol or triglyceride levels. The condition is widespread with approximately 35% of those over 18 years of age impacted—approximately 80 million people.

Another area of study is the potential for Lomecel-B to impact the lives of those with Acute Respiratory Distress Syndrome (ARDS), which is associated with Covid-19. ARDS is a life-threatening lung condition that impacts about 150,000 people a year and is particularly harmful to those with Aging Frailty. There are currently limited treatments for ARDS and we'll be watching to see if Lomecel-B can have a positive effect on those afflicted with ARDS.

THE COMPANY

Longeveron is clinical-stage biotechnology company developing cellular therapies for chronic diseases associated with aging and other life-threatening conditions. Management believes that by using the same cells that promote tissue repair, organ maintenance, and immune system function, the company can develop safe and effective therapies for some of the most difficult disorders associated with the aging process. As mentioned, Lomecel-B is the major treatment option being investigated for a variety of maladies and is obtained from fresh bone marrow tissue donated by adult donors. In light of the research completed to this point, we view the prospects of Lomecel-B as promising but uncertain. The uncertainty runs in several different camps. There is the uncertainty of approval of the Lomecel-B based therapy for any particular disease, and then, if approval does come, what revenues will be able to be generated—as most of the markets Longeveron is pursuing are relatively unknown in nature, with no existing treatments options and no cost or insurance payback comparisons available. There is also the risk that one or more of the competitors pursuing treatments in a variety of these areas will beat Longeveron to the commercialization phase in one or more cases.

We are encouraged by the funding situation of Longeveron. Funding can also be a limiting factor in clinical-stage companies and dilution of current shareholders often occurs as companies return to the equity market to keep their operations going. Longeveron converted from an LLC to Longeveron Inc. in February of 2021 and started public trading of LGVN on the NASDAQ. The IPO grossed \$26.6 million for the company and an over-allotment sale in March garnered another \$2.5 million. Management also recently, December 2021, announced a private placement agreement selling almost 1.2 million shares and warrants, with a purchase price of \$17.50, immediately exercisable, netting proceeds of \$18.6 million.

Management has stated that, beyond these moves, they are pursuing non-dilutive funding through grants, which has proven to be a fairly successful strategy to this point and a positive position to be in from our point of view, as since inception through September 30, 2021, the company has been awarded roughly \$11.9 million in government and non-profit association grants, the details of which are below:

Longeveron Grants

Project	Funding Source	Amount	Status
Aging Frailty Phase 2b Trial	SBIR, (DHHS), NIA	\$3,957,813	Complete
Aging Frailty Phase 2b Trial	SBIR, (DHHS), NIA	283,040	Complete
Alzheimer's Disease Phase I Trial	Alzheimer's Association	3,000,000	Complete
Alzheimer's Disease Phase I 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 Frailty Influenza Vaccine Trial ("HERA")	MSCRF-TEDCO	750,000	Complete
HLHS Phase I Trial	MSCRF-TEDCO	750,000	Complete
HLHS Phase 2 Trial	UG3 (DHHS) NHLBI	477,566	Ongoing
ARDS Phase I Trial	MSCRF-TEDCO	650,000	Ongoing

SBIR=Small Business Innovation Research;
 STTR=Small Business Technology Transfer;
 DHHS=Department of Health and Human
 Services;NIA=National Institute on Aging;
 NHLBI=National Heart, Lung and Blood; MSCRF-
 TEDCO=Maryland Stem Cell Research Fund

Longeveron does have several commitments to outside parties should certain therapies come to fruition. The company has a licensing agreement with the University of Miami for the use of certain stem cell aging-related frailty technology rights developed by the current Chief Science Officer while employed at UM. There are various minor payments due if certain milestones are reached and the company issued roughly 110,000 shares to UM and agreed to pay 3% of net sales or proceeds obtained from any products or services developed from the technology.

The company also has a licensing agreement with JMHMD Holdings, LLC—which is an affiliated entity of the CSO—for the use of CD271 cellular therapy technology. Longeveron agreed to pay a 1% royalty of the net annual sales of the licensed product.

And finally, the grant agreement with the Alzheimer's Association comes with the stipulation that Longeveron may be required to make revenue sharing payments to the Association for products or inventions generated by the Alzheimer's Disease Clinical Trial Program. Those payments are currently not defined but could result in a maximum payment of five times the award amount. We don't view these agreements as unreasonable or onerous and believe that Longeveron has set itself up well to be able to sustain itself for the foreseeable future and see the testing processes currently ongoing come to completion.

VALUATION

Longeveron is a company that can have valuations all over the board, depending on the assumptions made about approvals of various treatments, the timing of those approvals, and the acceptance in the marketplace of those therapies. We have tried to take a middle-of-the-road approach, not being overly optimistic on any of the therapies discussed, but believing that all mentioned therapies have at least a chance of making it to commercialization. But before we get into the assumptions we made, it must be noted that larger pharmaceutical companies have been aggressively looking to expand their pipelines and bring technology such as that used by Longeveron under their roofs. In our view, the further some of these treatments get along the approval process, the more attractive Longeveron will become to a potential acquirer. At that point, we don't know what price will be paid, but it can be assumed based on history that there will be at least a 20-40% premium above the prevailing market price at the time—something for investors to keep in mind as a possibility.

Looking past a potential acquisition, we place a valuation on LGVN of \$20.00. That valuation is based on the company's Hypoplastic Left Heart Syndrome treatment will come to market in 2028 and capture roughly 75% of the children that undergo surgery for the condition. We also place a 50% likelihood of that approval coming and being commercialized. For the other conditions, which are more difficult in our view to treat—Alzheimer's is notoriously difficult to find the cause of and insurance companies may be reluctant to pay for a treatment that may only have modest benefits. And Aging Frailty disease is not even classified as a disease by the FDA at this point, making it unlikely that insurance companies would want to pay for treatment or even that treatment would be approved. Having said that, we also believe that the company's management is doing good work in working with the authorities to further explain the condition and that Aging Frailty may be a recognized condition in the not-too-distant future.

With these challenges in place, although the potential markets are large as discussed above, we believe that the uptake of any potential approved therapy will be relatively low initially and ramp up only gradually. Therefore, we give both the Alzheimer's and Aging Frailty treatments a 10% chance each of making it to market and both treatments being commercialized in 2029.

After these treatments are approved and in the market, we are assuming a 5% annual gain in revenue from all treatments, with bumps from international market royalties once the treatments get approved overseas. Given the positive trial results to this point, but also recognizing the challenges that remain, we use a relatively high discount rate of 20% in the discounted cash flow model, reflecting the higher risk premium we believe investors should place on LGVN.

All of this results in a valuation of \$20.00 per share, below which we believe would be a good investment opportunity for investors who are willing to ride some inevitable volatility and have a relatively high risk tolerance.

RISKS

- Longeveron has no approved products at this point in time and no incoming revenue from the commercialization of any therapy—making future prospects and appropriate valuation more difficult to ascertain.
- According to the company, the FDA and the Japanese drug approval authority have indicated that the concept of frailty as an indication will require additional clinical data and discussion before future pivotal trials.
- Cell-based therapies are a relatively new area of potential treatment and could complicate or delay the approval process of Lomecel-B for various conditions. As of now, there are no FDA-approved cell-based therapies for aging frailty, Alzheimer’s disease or Hypoplastic Left Heart Syndrome.
- Also related to the novelty of cell-based therapy, the market may be slow to adopt and accept these therapies even if after they have received FDA approval.
- Longeveron relies on a select cohort of human donors of bone marrow, between 18-45, prescreened for health conditions, and limited to 6 lifetime donations, for the material needed for Lomecel-B and finding the needed number of approved donors may be difficult as demand grows.
- Funding for Longeveron’s activities is reliant upon financing activities and governmental sources, neither of which are certain and could cause Longeveron to run into funding issues should either of those sources end or substantially decline. Additionally, should management decide to issue substantial new shares of stock in Longeveron to achieve needed operating capital, existing shareholder holdings would be diluted.

MANAGEMENT

Geoff Green (Chief Executive Officer) has been with Longeveron since 2016, first as Senior Vice President of Clinical Operations (2016 – 2018), and then as President and as Chief Executive Officer (2019 – present). Mr. Green is a versatile life sciences executive with over 20 years in leadership roles spanning clinical drug development, clinical operations, and business development. Prior to joining Longeveron, he was VP of Operations at Partikula, VP, Business Development & Clinical Affairs at Accu-Break Pharmaceuticals, President and Acting CEO of DOR BioPharma (now Soligenix (NAS: SNGX)), VP of Business Development & Operations at Heart Genomics, and Director of Clinical Affairs at Innovative Drug Delivery Systems. Early in his career he spent several years managing oncology clinical trials at Memorial Sloan-Kettering Cancer Center, and as a research associate at Paramount Capital, where he managed clinical trials for several portfolio companies. Mr. Green received a B.A. in biology from Kenyon College, and an M.B.A. from Barry University’s Andreas School of Business.

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A. (Co-Founder, Chief Science Officer and Chairman) co-founded Longeveron in 2014 and has served on its Board of Directors and as its Chief Science Officer since that time. Longeveron obtained an exclusive license to cell production technologies developed by Dr. Hare at UM. Dr. Hare is a double boarded cardiologist (Cardiology and Advanced Heart Failure and Transplantation) and is the founding director of the Interdisciplinary Stem Cell Institute at the UM Miller School of Medicine. He has obtained in excess of \$25 Million in funding from the National Institutes of Health over the past 15 years to support basic research of cell therapy strategies. He is also a recipient of the Paul Beeson Physician Faculty Scholar in Aging Research Award, and is an elected member of the American Association of Physicians, The American Society for Clinical Investigation, and is an elected Fellow of the American Heart Association. Dr. Hare has

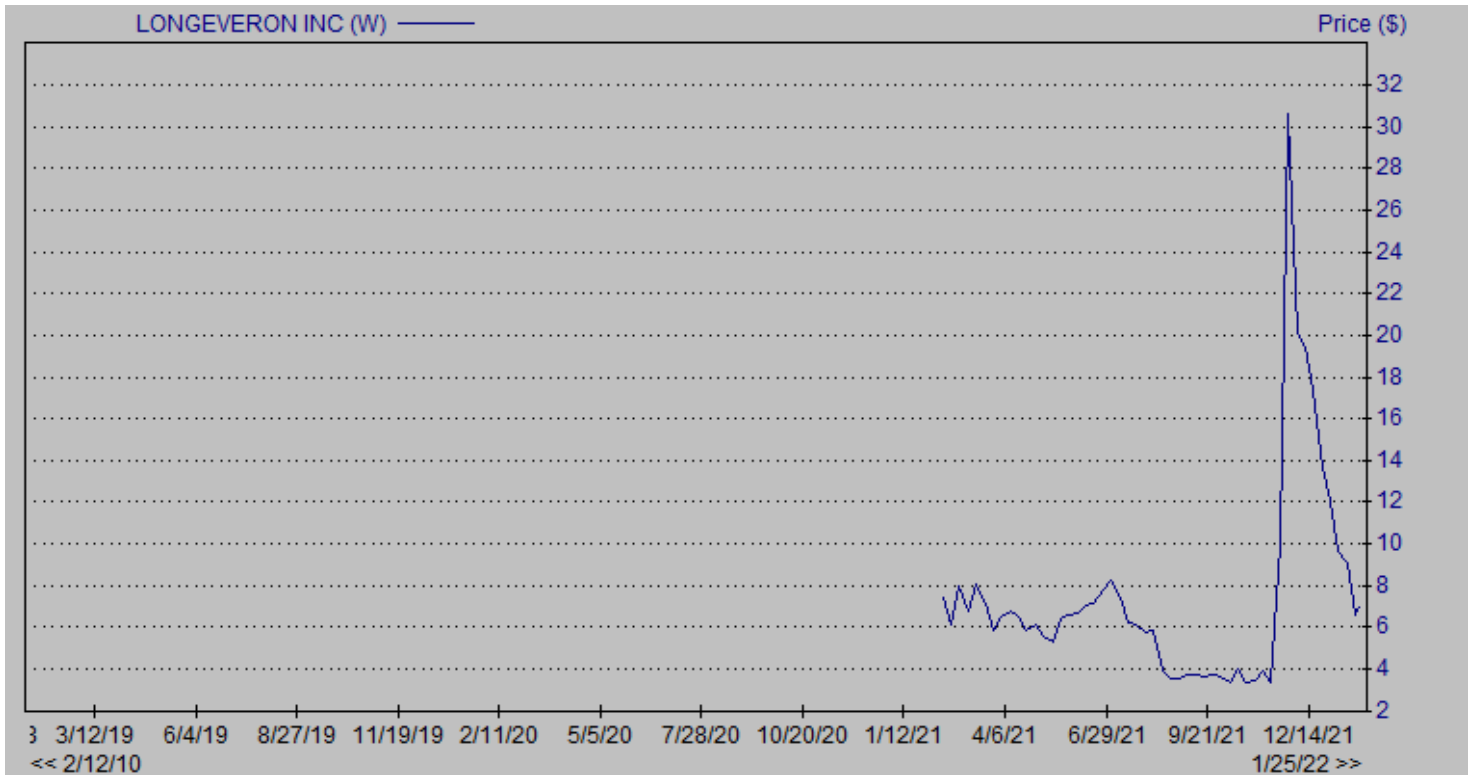
also served in numerous leadership roles at the American Heart Association and at the Center for Scientific Review of the National Institutes of Health. Dr. Hare is also a co-founder of Vestion, Inc., and Heart Genomics, LLC, companies that hold cardio-related intellectual property. He received a B.A. from the University of Pennsylvania, and his MD from The Johns Hopkins University School of Medicine and completed fellowships at Johns Hopkins and Brigham and Women's Hospital, and was a Research Fellow at Harvard Medical School.

James Clavijo (Chief Financial Officer) joined Longeveron in 2019. He has over 25 years of experience in executive, finance and accounting activities, including experience as a Chief Financial Officer for several pharmaceutical, healthcare and manufacturing companies. Mr. Clavijo's experience has included building, leading and advising companies with strategic plans for pharmaceutical commercialization and manufacturing, negotiating licensing and drug development agreements, as well as advising companies with complex restructurings, mergers and acquisitions, capital market transactions, and system implementations. During 2018, Mr. Clavijo served as the Chief Financial Officer for Aeterna Zentaris (NASDAQ: AEZS). Prior to this, Mr. Clavijo served for two years as the Chief Financial Officer for Tri-source Pharma, a pharmaceutical company focused on procuring pharmaceutical products facing supply issues and supplying pharmaceutical products to veterinary markets. Since 2009, Mr. Clavijo, has also served as founder and principal of Barcelona Capital Partners, a consulting firm that provided Chief Financial Officer services, which include the preparation of regulatory filings with the Securities and Exchange Commission. Previously, Mr. Clavijo served for five years as the Chief Accounting Officer at Soligenix (NASDAQ: SNGX), a public biopharmaceutical company. In addition, Mr. Clavijo worked for Deloitte & Touche and was an Officer in the U.S. Army, serving for 13 years in active and reserve duty. Mr. Clavijo was licensed as a CPA in Florida from 2000-2011. He is licensed in Florida as a real estate/business agent since 2013. Mr. Clavijo received a B.A. in Chemistry (PreMed) from the University of Florida, a B.A. in Accounting from the University of Nebraska, and a Masters in Accounting from Florida International University.

INCOME STATEMENT & BALANCE SHEET

Longeveron Income Statement and Balance Sheet								
(in thousands, except per share data)								
	1Q2021A	2Q2021A	3Q2021A	4Q2021E	2022E	2023E	2024E	
Revenues								
Grant Revenue	211	275	68	60	700	950	875	
Clinical Trial Revenue	165	214	164	170	402	405	410	
Contract Revenue	0	0	0	0	0	0	0	
Total Revenues	376	489	232	230	1,102	1,355	1,285	
Cost of Revenues	227	281	68	75	400	404	408	
Gross Profit	149	208	164	155	702	951	877	
Operating Expenses								
General and administrative	2201	3257	2,996	3,000	10,650	11,250	11,550	
Research and development	1350	1960	2,048	2,105	5,150	5,550	5,825	
Selling and marketing	56	53	25	29	110	110	175	
Total operating expenses	3,607	5,270	5,069	5,134	15,910	16,910	17,550	
Loss from operations	(3,458)	(5,062)	(4,905)	(4,979)	(15,208)	(15,959)	(16,673)	
Other income and (expenses)								
Interest expense		-2	(1)	(1)	(2)	(3)	(3)	
Other income, net	347	54	51	51	205	207	209	
Total other income and (expenses), net	347	52	50	60	203	204	206	
Net loss	(3,111)	(5,010)	(4,855)	(4,919)	(15,005)	(15,755)	(16,467)	
Basic and diluted loss per share	\$ (0.18)	\$ (0.26)	\$ (0.25)	\$ (0.25)	\$ (0.74)	\$ (0.74)	\$ (0.74)	
Basic and diluted wtd avg common shares	17,491,066	19,005,007	19,115,152	19,306,304	20,271,619	21,285,200	22,349,460	
Assets								
Current Assets:								
Cash	24,461	16,833	9,738	9,250	9,713	10,098	10,401	
Other Current assets	836	5,278	9,927	6,425	5,250	5,355	5,409	
Total Current Assets	25,297	22,111	19,665	15,675	14,963	15,453	15,809	
Property, Plant and Equipment, net	3,417	3,234	3,070	2,917	2,771	2,632	2,501	
Intangible assets, net	1,533	2,390	2,358	2,382	2,405	2,429	2,454	
Right-of-use (ROU) Asset	2,008	1,945	1,880	1,786	1,697	1,527	1,451	
Other	177	177	177	177	177	177	177	
Total Assets	32,432	29,857	27,150	22,936	22,012	22,219	22,391	
Liabilities and stockholder equity								
Current liabilities:								
Accounts Payable	895	149	361	379	398	727	807	
Accrued Expenses	961	1,277	834	953	772	625	875	
Current portion of lease	517	524	530	530	530	520	530	
Short-term note payable	19	-	-	-	-	-	-	
Current portion of loans	4	5	5	5	5	5	5	
Deferred Revenue	385	230	202	202	202	202	222	
Total Current Liabilities	2,781	2,185	1,932	2,069	1,907	2,079	2,439	
Long-term Liabilities:								
Long-term loans	146	145	143	143	142	140	138	
Lease Liability	3,010	2,877	2,742	2,687	2,418	2,346	2,276	
Total long-term liabilities	3,156	3,022	2,885	2,830	2,560	2,486	2,414	
Total liabilities	5,937	5,207	4,817	4,899	4,467	4,565	4,853	
Stockholders Equity								
Members equity	19	19	19	19	19	19	19	
Additional Paid-in capital	56,580	59,745	62,283	62,906	77,509	93,283	109,634	
Stock Subscription receivable	(100)	(100)	(100)	(100)	(100)	(100)	(100)	
Accumulated Deficit	(30,004)	(35,014)	(39,869)	(44,788)	(59,793)	(75,548)	(92,015)	
Total stockholders equity	26,495	24,650	22,333	18,037	17,635	17,654	17,538	
Total liabilities and stockholder equity	32,432	29,857	27,150	22,936	22,102	22,219	22,391	

HISTORICAL STOCK PRICE



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