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Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Positive updates on trials and good balance sheet encouraging.

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 reiterate our $20.05 valuation on LGVN using the discounted cash flow model.

Current Price (08/11/22)	$5.94
Valuation	**$20.05**

OUTLOOK

Longeveron reported a 2Q 2022 loss of $0.27/per share, slightly worse than last year in the same period but within the range of expectations.

More importantly, Longeveron provided updates on numerous trials. The Phase 2a trial of Lomocel-B for the treatment of Alzheimer's remains on track and the Aging Frailty trial met the primary safety endpoint.

SUMMARY DATA

52-Week High	**$42.30**
52-Week Low	**$2.92**
One-Year Return (%)	**9.80**
Beta	**-.053**
Average Daily Volume (sh)	**157,968**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$124**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**42**
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	**-8.5**
P/E using 2023 Estimate	**-8.0**
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	0.4 A	0.5 A	0.2 A	0.2 A	1.4 A
2022	0.4 A	0.5 A	0.2 E	0.4 E	1.2 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	-$0.20 A	-$0.90 A
2022	-$0.17 A	-$0.27 A	-$0.20 E	-$0.10 E	-$0.70 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

Updates

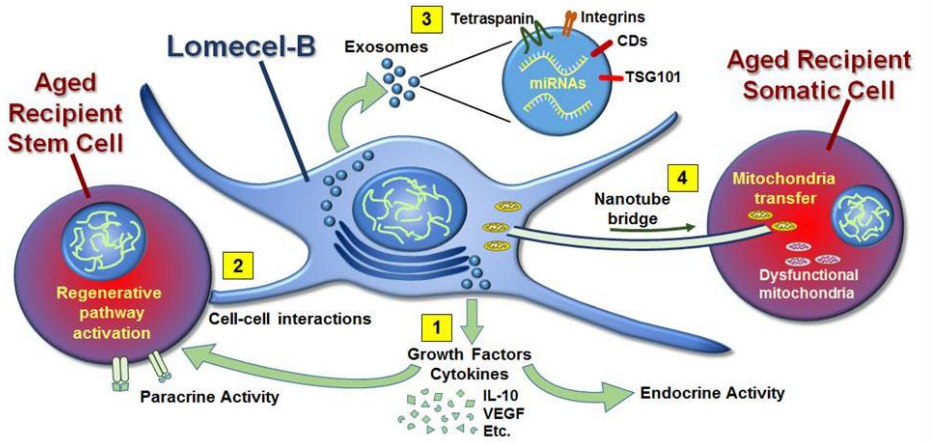
- Longeveron (LGVN) reported 2Q 2022 revenues of $0.5 million, in line with the same quarter a year ago, and a loss of $0.27/per share, mostly inline with expectations.
    - No surprises in the financial releases for 2Q and things appear to remain on track, with no major concerns.
- The company also reported an ending cash balance, as of June 30, 2022, of $27 million.
    - Management believes this cash balance will be adequate to cover expenses and capital expenditures into the first half of 2024.
- The Phase 2a clinical trial of Lomecel-B to evaluate the safety of the drug in patients with mild Alzheimer's Disease is at 50% enrollment and on track for complete enrollment by the end of 2022.
- The company provided updates on its progress in using Lomecel-B in the treatment of aging frailty disease announced top-line findings from the second phase of the Phase ½ HERA trial, which met the primary endpoint for safety.
    - Management noted that the company plans to pursue additional studies of the immune system as it continues to study the range of impacts Lomecel-B has the potential to have on aging frailty.
- The company is pursuing approval of Lomecel-B in the treatment of Aging Frailty disease with the Japanese medical authority that would allow them to enter the market in Japan on an accelerated basis.
- These updates were given by the interim CEO, as the company continues to search for new, permanent CEO.

Lomecel-B

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 May 10, 2022

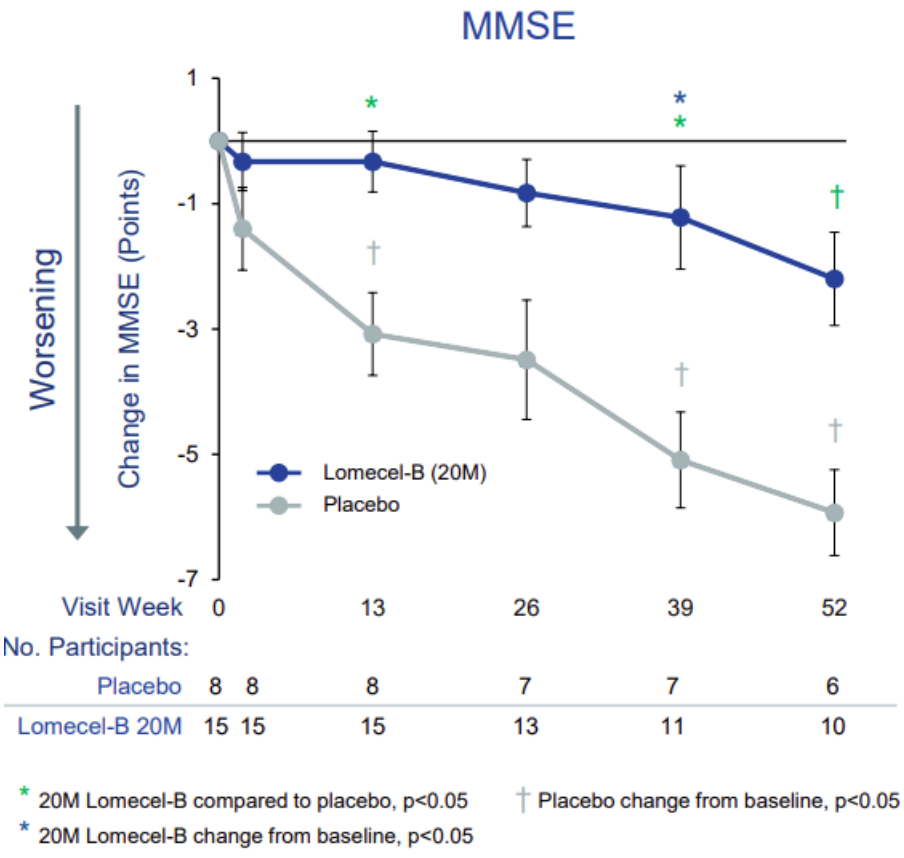
Alzheimer's Disease

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 now enrolling subjects for the Phase 2a clinical trial, which is designed to evaluate the safety of single and multiple administrations of two different doses of Lomecel-B. Enrollment in that

study is on track and expected to be completed by the end of 2022. Additionally, the company presented a poster of the trial at the Alzheimer's Association International Conference (AAIC). 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. Longeveron published the results from the Phase I trial in Alzheimer's & Dementia: The Journal of the Alzheimer's Association, confirming the positive results.

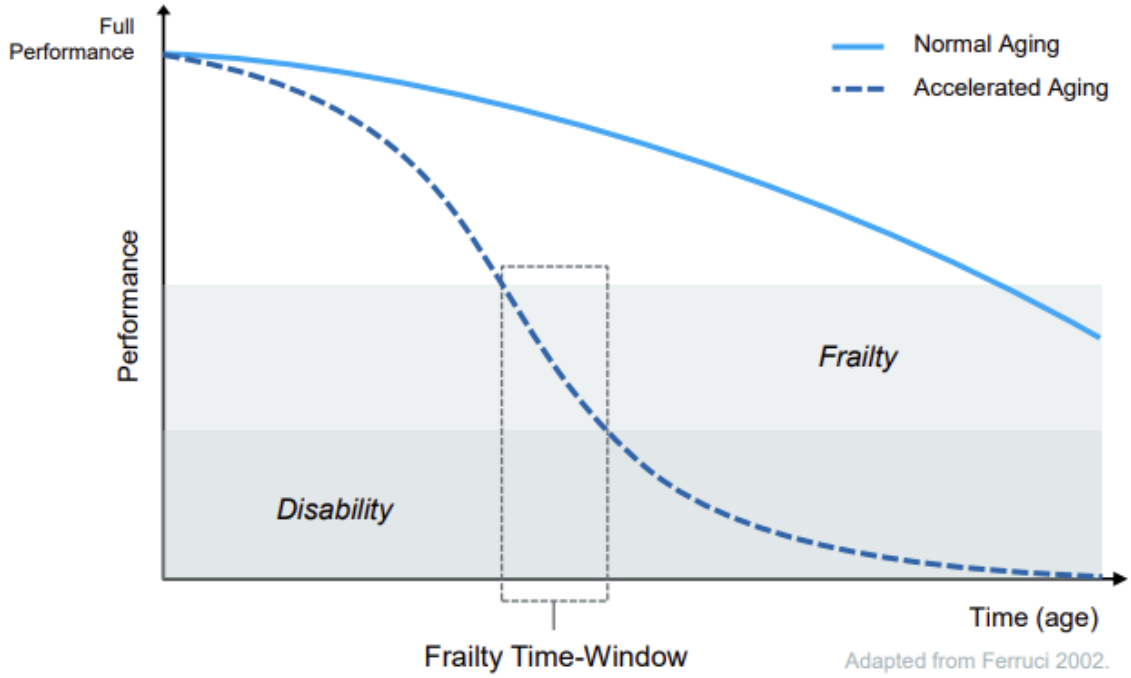


MMSE: Mini Mental State Exam; **20M:** 20 million.

Source: https://www.longeveron.com May 10, 2022

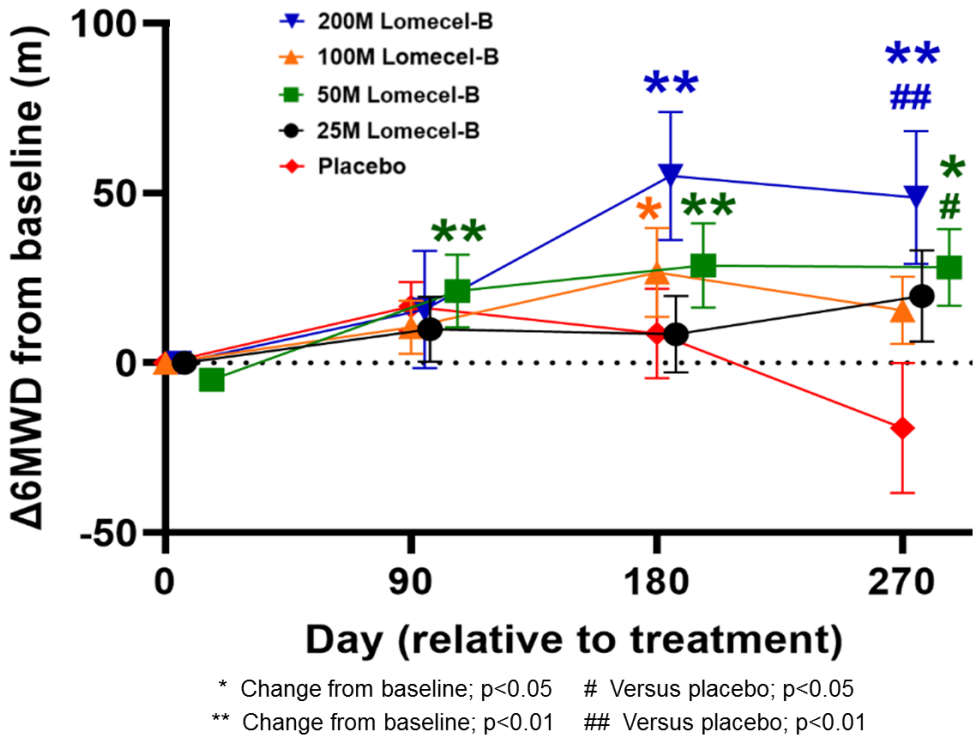
Aging Frailty Research Program

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

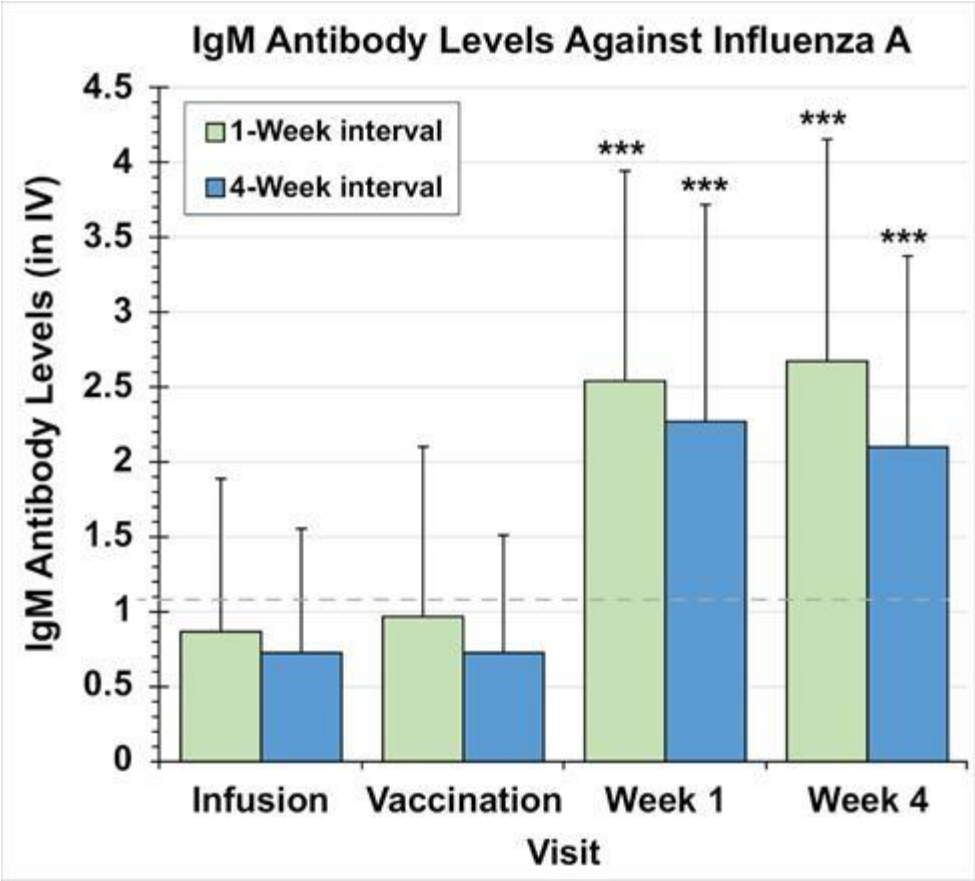
And it's not an uncommon condition with various studies cited by Longeveron, including one from John Hopkins, suggesting that approximately 15% of individuals in the US above 65 years of age are impacted, which equates to roughly 8.1 million people. And of course, there are aging populations all over 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)



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. The company announced in August 2022 that the second phase of the Phase ½ HERA trial met the primary endpoint for safety. 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.



***-p<0.001; Source: https://www.longeveron.com December 9, 2021

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.

RISKS

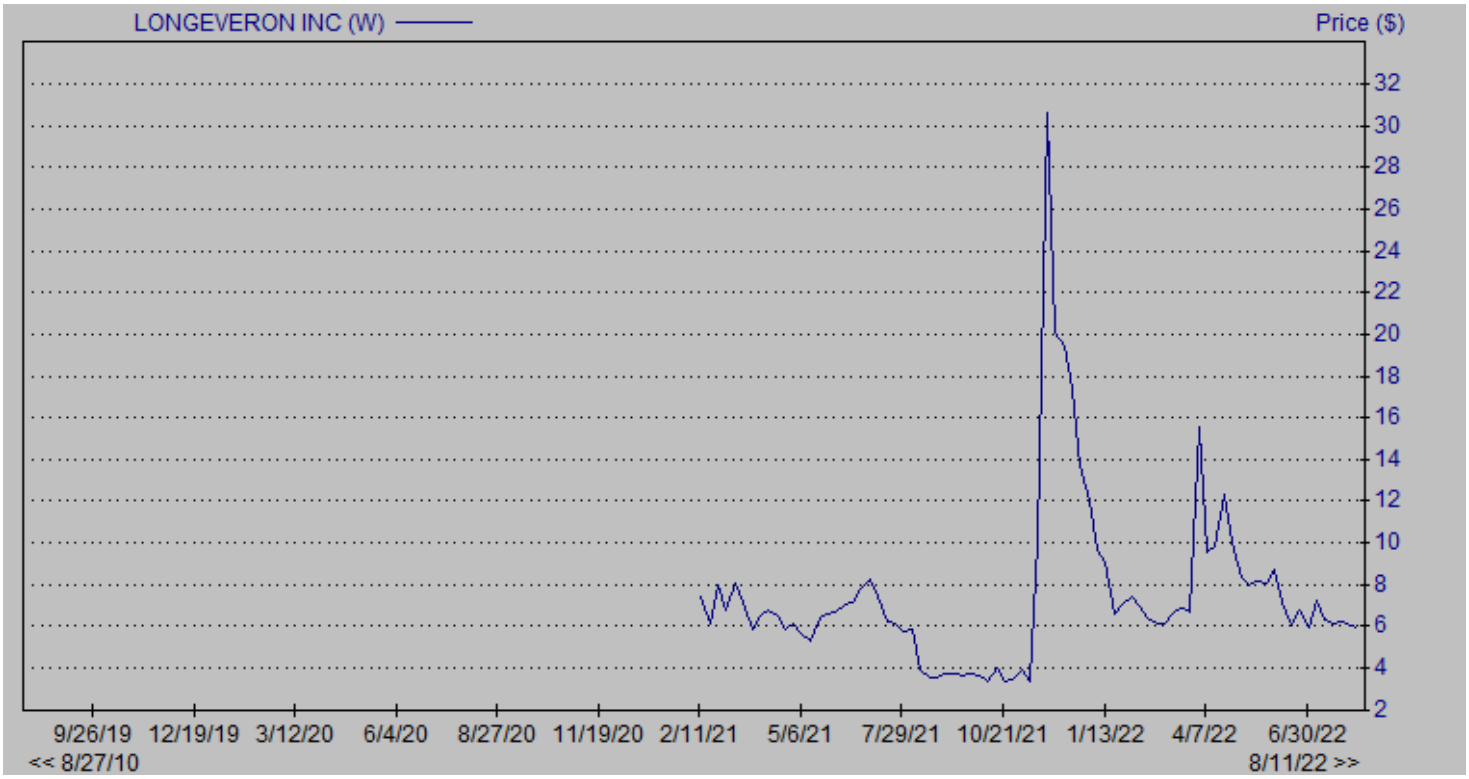
- The CEO departure has left a void in leadership that concerns us slightly and we will be watching the process and outcome of the process of the search for the company's new CEO.
- Longeveron has no approved products at this point in time and no incoming revenue from the commercialization of any therapy—making 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.

INCOME STATEMENT & BALANCE SHEET

Longeveron Income Statement and Balance Sheet									
(in thousands, except per share data)									
		2Q2021A	**3Q2021A**	**4Q2021A**	**1Q2022A**	**2Q2022A**	**2022E**	**2023E**	**2024E**
Revenues									
	Grant Revenue	275	68	44	60	126	700	950	875
	Clinical Trial Revenue	214	164	165	310	340	402	405	410
	Contract Revenue	0	0	0	0	0	0	0	0
Total Revenues		489	232	209	370	466	1,102	1,355	1,285
	Cost of Revenues	281	68	140	70	306	400	404	408
Gross Profit		208	164	69	300	160	702	951	877
Operating Expenses									
	General and administrative	3257	2,996	2,280	1,980	2427	10,650	11,250	11,550
	Research and development	1960	2,048	1,733	1,427	1720	5,150	5,550	5,825
	Selling and marketing	53	25	88	287	234	110	110	175
Total operating expenses		5,270	5,069	4,101	3,694	4,381	15,910	16,910	17,550
Loss from operations		(5,062)	(4,905)	(4,032)	(3,394)	(4,221)	(15,208)	(15,959)	(16,673)
Other income and (expenses)									
	Interest expense	-2	(1)	(1)	0	0	(2)	(3)	(3)
	Other income, net	54	51	(36)	(116)	-1403	205	207	209
Total other income and (expenses), net		52	50	(37)	(116)	(1,403)	203	204	206
Net loss		(5,010)	(4,855)	(4,069)	(3,510)	(5,624)	(15,005)	(15,755)	(16,467)
Basic and diluted loss per share		$ (0.26)	$ (0.25)	$ (0.20)	$ (0.17)	$ (0.27)	$ (0.71)	$ (0.71)	$ (0.71)
Basic and diluted wtd avg common shares		19,005,007	19,115,152	20,019,138	20,911,203	20,943,897	21,020,095	22,071,100	23,174,655
Assets									
Current Assets:									
	Cash	16,833	9,738	25,658	22,132	20,224	25,503	25,576	25,692
	Short-term investments	5,278	9,927	9,333	8,449	6,837	8,702	8,964	9,232
Total Current Assets		22,111	19,665	34,991	30,581	27,061	34,205	34,540	34,924
Property, Plant and Equipment, net		3,234	3,070	3,062	2,966	2,835	2,909	2,763	2,625
Intangible assets, net		2,390	2,358	2,334	2,361	2,358	2,357	2,381	2,405
Other assets		2,122	2,057	2,379	3,265	3,071	2,260	2,034	1,932
Total Assets		29,857	27,150	42,766	39,173	35,325	41,732	41,718	41,887
Liabilities and stockholder equity									
Current liabilities:				Details estimated	Details estimated	Details estimated			
	Accounts Payable	149	361	501	505	895	526	727	807
	Accrued Expenses	1,277	834	1,150	900	961	772	625	875
	Current portion of lease	524	530	530	520	517	530	520	530
	Short-term note payable	-	-	-	-	19	-	-	-
	Current portion of loans	5	5	5	5	5	5	5	5
	Deferred Revenue	230	202	202	202	202	202	202	222
Total Current Liabilities		2,185	1,932	2,388	2,132	2,599	2,035	2,079	2,439
Long-term Liabilities:									
	Long-term loans	145	143	143	143	146	142	140	138
	Lease Liability	2,877	2,742	2,782	2,592	3,199	2,504	2,429	2,356
Total long-term liabilities		3,022	2,885	2,925	2,735	3,345	2,646	2,569	2,494
Total liabilities		5,207	4,817	5,313	4,867	5,944	4,681	4,648	4,933
Stockholders Equity									
	Members equity	19	19	19	19	19	19	19	19
	Additional Paid-in capital	59,745	62,283	62,906	63,535	59,466	77,509	93,283	109,634
	Stock Subscription receivable	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
	Accumulated Deficit	(35,014)	(39,869)	(25,372)	(29,148)	(30,004)	(40,377)	(56,132)	(72,599)
Total stockholders equity		24,650	22,333	37,453	34,306	29,381	37,051	37,070	36,954
Total liabilities and stockholder equity		29,857	27,150	42,766	39,173	35,325	41,732	41,718	41,888

HISTORICAL STOCK PRICE



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