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Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Trial Results 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 place a value of $10.45 on LGVN using the discounted cash flow model.

Current Price (02/2526)	$0.55
Valuation	**$10.45**

OUTLOOK

Longeveron is focusing on using its primary treatment, laromestrocel, to fight a rare pediatric heart birth defect that devastates families and continues to receive good FDA news regarding its treatment for Alzheimer's Disease, while also expanding its pipeline.

The company announced trial results from its Phase 2b clinical trial that showed laromestrocel improved the physical condition of patients with age-related clinical therarpy.

SUMMARY DATA

52-Week High	**$1.86**
52-Week Low	**$0.50**
One-Year Return (%)	**-63.67**
Beta	**0.21**
Average Daily Volume (sh)	**367,147**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**11**
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 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0.4 A	0.5 A	0.3 A	0.1 A	1.2 A
2023	0.3 A	0.2 A	0.2 A	0.0 A	0.7 A
2024	0.5 A	0.5 A	0.8 A	0.6 A	2.3 A
2025	0.4 A	0.3 A	0.1 A	0.3 E	1.1 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.17 A	-$0.27 A	-$0.25 A	-$0.21 A	-$0.90 A
2023	-$0.22 A	-$0.27 A	-$0.28 A	-$0.25 A	-$1.02 A
2024	-$1.61 A	-$1.83 A	-$0.34 A	-$0.48 A	-$2.26 A
2025	-$0.34 A	-$0.33 A	-$0.39 A	-$0.42 E	-$1.48 E

Update

Longeveron is a clinical-stage biotechnology company that has positioned itself in the regenerative medicine space with a potentially life-changing therapeutic candidate. Its flagship product, laromestrocel, is an allogeneic medicinal-signaling cell (MSC) therapy derived from young healthy adult donors and manufactured under current good manufacturing practice The science behind laromestrocel rests on the idea that these MSCs may provide anti-inflammatory, pro-vascular and regenerative support in tissues that are damaged or under stress. The company behind these exciting developments is at an inflection point in our view, with a good opportunity to achieve many of the goals discussed in the near future.

While the company is advancing multiple clinical programs (including efforts in Alzheimer's disease and age-related frailty), the HLHS program stands out for both its compelling early data and regulatory momentum.

Although treating HLHS is the primary condition Longeveron is focused on, it certainly isn't the only one. Company management recently announced results from is Phase 2b clinical trial using laromestrocel as a treatment for Age-Related Frailty. Age-Related Frailty is a clinical condition seen most commonly in older adults that reflects a decline in physiological reserves across multiple body systems. It's not a single disease but a syndrome marked by weakness, fatigue, slow walking speed, unintentional weight loss, and reduced ability to cope with stressors like illness or injury. People living with frailty are more vulnerable to falls, disability, hospitalizations, and loss of independence because their bodies can't respond as effectively to challenges as they once could. Estimates of how many people suffer from frailty vary depending on the definition used and the population studied, but research indicates that in community-dwelling older adults (typically defined as age 65 and older), about 7–16% are frail using commonly accepted criteria-a significant number of people. Trial results from Longeveron showed that laromestrocel improved the physical condition of patients with frailty after nine months compared with placebo. The main data point is the 6-minute walk test, which saw a meaningful 63 meter improvement compared to placebo, which is a substantial improvement and indicates great promise that laromestrocel can improve the lives of thousands of patients.

We also want to remind investors of the progress made on treating HLHS, which is a rare and life-threatening congenital heart defect in which the left ventricle is severely under-developed or absent, meaning that the right ventricle must be adapted to handle systemic circulation. Even with the standard of care—typically a series of three reconstructive surgeries over the first few years of life—survival into adolescence is only around 50–60%.

Longeveron's approach has been to administer laromestrocel directly into the right ventricle (or the myocardium of the right ventricle) during the second stage of surgery (the "Glenn" procedure, typically at around 4 months of age). Company scientists believe that by improving the function of the systemic right ventricle—through regenerative mechanisms—the therapy should improve transplant-free survival and long-term outcomes for these infants.

The company reported Phase 1 results (called ELPIS I) in ten infants. In that study, laromestrocel was well tolerated: there were no major adverse cardiovascular events or infections related to therapy through one year, meeting the primary safety endpoint. Even more striking, long-term follow-up showed 100 % transplant-free survival up to five years in those patients, compared to historical controls (approximately 83 % at five years, with ~5 % requiring transplant) in the comparable population.

Building on that, Longeveron is now conducting a pivotal Phase 2b trial (ELPIS II). The trial is designed to compare Laromestrocel plus standard surgery versus standard surgery alone, with endpoints including

survival at 12 months, length of hospitalization and change in right ventricular ejection fraction between baseline and 12 months. Full enrollment was achieved in June 2025, with topline results, as mentioned above, anticipated in the third quarter of 2026 after a 12-month follow-up.

On the regulatory front, the program has very strong designations. The U.S. Food and Drug Administration has approved three special designations for laromestrocel in the HLHS indication: Rare Pediatric Disease (RPD) designation, Orphan Drug Designation (ODD), and Fast Track designation. Importantly, following a Type C meeting with FDA in September 2024, the agency confirmed that the ELPIS II trial could serve as a pivotal study—and if positive, could form the basis for a Biologics License Application (BLA) submission for full traditional approval.

Company management continues to push the company forward, recently announcing that LGVN has licensed a patent from the University of Miami that protects a method to derive GHRH-Receptor+ cardiomyogenic cells from pluripotent stem cells. In plain English, these cells are able to differentiate into human cardiac muscle cells. This creates the potential for a treatment that is safer than existing techniques to derive new cardiac heart muscle cells. This move by management appears to us to be a perfect compliment to the company's existing treatment line and should advance the company's ability to treat devastating heart conditions.

That's not the only line of treatment being pursued by the company as management recently announced that it completed a "positive" Type B Meeting with the FDA regarding advancing laromestrocel for the purpose of treating Alzheimer's Disease. During the meeting, the FDA and the company reached alignment on the study design for a single, pivotal, seamless adaptive Phase 2/3 clinical trial. Additionally, something we always like to hear about the approval process, the FDA agreed to consider a Biological License Application (BLA) based on positive interim trial results, which accelerate the path to what we believe will be the approval of laromestrocel as a treatment for Alzheimer's.

As a reminder, our optimism is well founded based on trial results that we've written about recently. For example, the Phase 2a CLEAR-MIND study results showed a favorable safety profile, absence of amyloid-related imaging abnormalities (ARIA) with Laromestrocel TM administration, and several domains of potential clinical efficacy, including cognition, function, quality of life, and reduction in brain atrophy. The results of the CLEAR-MIND trial formed the basis for the FDA RMAT designation. Another reminder that the RMAT designation is an important milestone, allowing the company better access to the FDA and accelerating the pathway to approval.

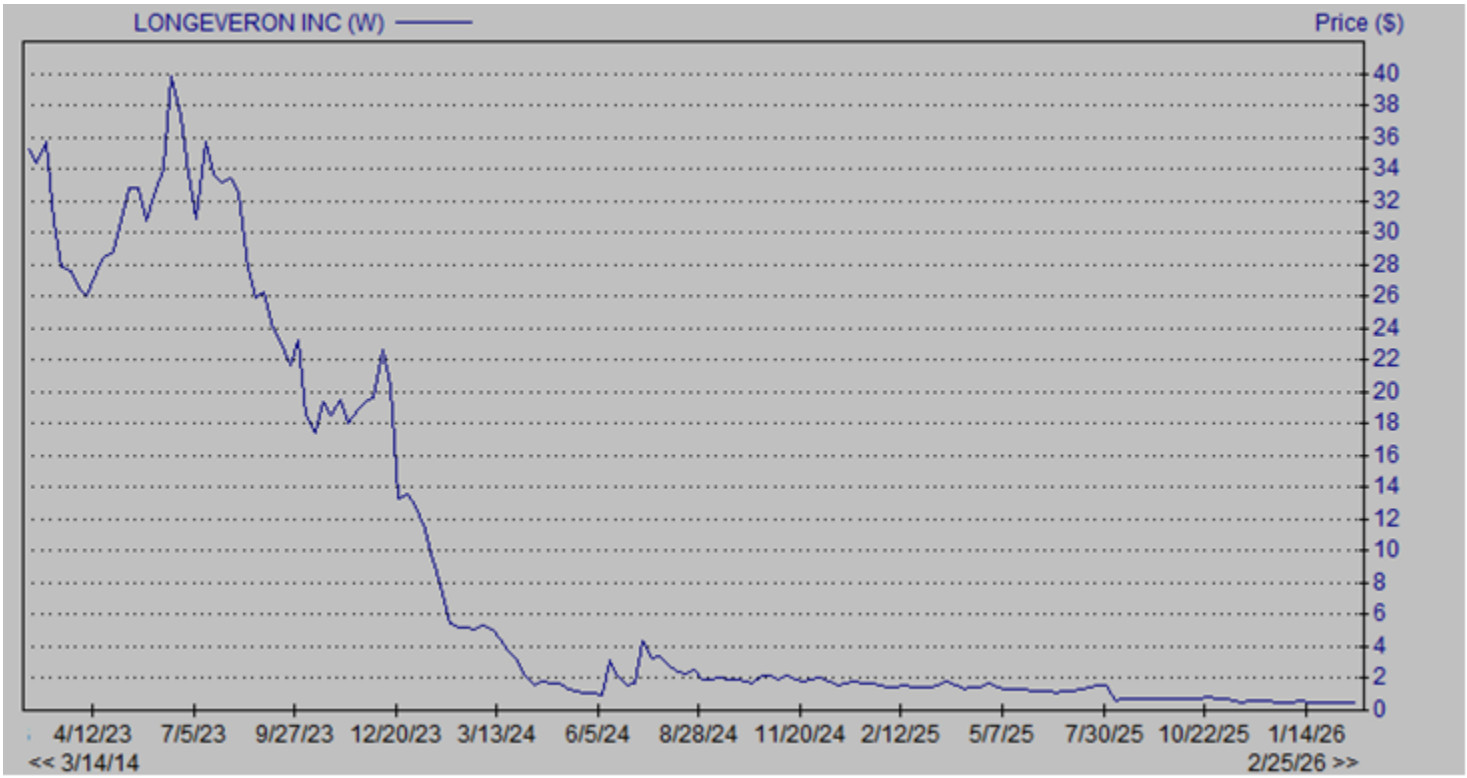
Summary

We continue to believe that Longeveron is an exciting clinical-stage company, and investors aren't appropriately appreciating the game-changing potential laromestrocel may be able to have on multiple serious medical conditions. As a result of the prudent decisions made by management, we believe laromestrocel will ultimately have a substantial impact on the health situations of thousands of patients. We believe the stock continues to be underpriced as investors aren't appreciating the potential of laromestrocel and encourage investors to take a look at LGVN.

PROJECTED INCOME STATEMENT & BALANCE SHEET

Longeveron Income Statement and Balance Sheet											
(US $ in thousands, except per share data)											
		1Q2025A	2Q2025A	3Q2025A	4Q2025E	1Q2026E	2Q2026E	3Q2026E	4Q2026E	2027E	2028E
Revenues											
	Sales	0	0	0	0	0	0	0	0	1000	1500
	Grant Revenue	0	0	0	0	0	0	0	0	0	0
	Clinical Trial Revenue	259	298	100	102	515	287	210	390	408	416
	Contract Manufacture Revenue	122	18	37	38	33	181	563	213	151	154
Total Revenues		381	316	137	140	548	468	773	603	559	2,070
	Cost of Revenues	106	170	12	77	219	124	91	74	307	1139
Gross Profit		275	146	125	63	329	344	682	529	252	932
Operating Expenses											
	General and administrative	2,941	2,589	3,583	3,690	2,768	2,823	2,880	2,937	14,762	15,205
	Research and development	2,515	2,954	3,852	4,237	2,219	2,286	2,354	2,425	16,949	17,457
	Selling and marketing	0	0	0	0	0	0	0	0	0	0
Total operating expenses		5,456	5,543	7,435	7,928	4,987	5,109	5,234	5,362	31,711	32,662
Loss from operations		(5,181)	(5,397)	(7,310)	(7,865)	(4,658)	(4,765)	(4,552)	(4,833)	(31,459)	(31,731)
Other income and (expenses)											
	Interest expense	0	0	0	0	0	0	0	0	0	0
	Other income, net	170	369	89	90	32	87	230	200	500	550
Total other income and (expenses), net		170	369	89	90	32	87	230	200	500	550
Net loss		(5,011)	(5,028)	(7,221)	(7,775)	(4,626)	(4,678)	(4,322)	(4,633)	(30,959)	(31,181)
Dividend attributable to warrant inducement		0	0	0	0	0	(8,501)	(149)	0	0	0
Basic and diluted loss per share		$ (0.34)	$ (0.33)	$ (0.39)	$ (0.42)	$ (1.84)	$ (2.02)	$ (0.33)	$ (0.49)	$ (1.65)	$ (1.65)
Basic and diluted wtd avg common shares		14,950,734	15,013,072	18,373,198	18,556,930	2,516,587	6,509,881	13,627,793	9,411,164	18,742,499	18,929,924
Assets											
Current Assets:											
	Cash	14,327	10,334	9,244	7,395	7,469	7,693	7,924	8,162	8,407	8,659
	Securities and other current assets	948	935	1,096	1,129	1,174	1,221	1,270	1,321	1,373	1,428
Total Current Assets		15,275	11,269	10,340	8,524	8,643	8,914	9,194	9,482	9,780	10,087
Property, Plant and Equipment, net		2,288	2,258	2,122	2,016	2,348	2,371	2,622	2,449	1,915	1,819
Intangible assets, net		2,291	2,321	2,309	2,332	2,263	2,353	2,347	2,401	2,355	2,379
Other assets		994	901	786	747	1,329	1,395	1,465	1,538	1,615	1,696
Total Assets		20,848	16,749	15,557	13,619	14,583	15,034	15,628	15,871	15,666	15,982
Liabilities and stockholder equity											
Current liabilities:											
	Accounts Payable	367	700	1,080	1,102	1,146	1,191	1,239	1,289	1,340	1,394
	Accrued Expenses	1,647	1,905	3,173	3,332	3,398	3,466	3,536	3,606	3,678	3,752
	Current portion of lease	631	639	647	530	504	478	454	432	410	390
	Short-term note payable	-	-	-	-	-	-	-	-	-	-
	Current portion of loans	-	-	-	-	-	-	-	-	-	-
	Deferred Revenue	79	40	40	44	826	397	118	40	48	53
Total Current Liabilities		2,724	3,284	4,940	5,007	5,873	5,533	5,347	5,367	5,477	5,589
Long-term Liabilities:											
	Long-term loans	-	-	-	-	-	-	-	-	-	-
	Other Liabilities	-	308	315	-	-	-	-	-	-	-
	Lease Liability	966	501	336	326	1,295	1,140	983	824	316	307
Total long-term liabilities		966	809	651	326	1,295	1,140	983	824	316	307
Total liabilities		3,690	4,093	5,591	5,333	7,168	6,673	6,330	6,191	5,793	5,895
Stockholders Equity											
	Members equity	14	14	19	6	3	8	13	14	7	8
	Additional Paid-in capital	131,762	132,288	136,813	138,181	92,080	115,859	131,139	131,480	139,563	140,959
	Stock Subscription receivable	-	-	1	3	-	-	-	-	4	5
	Accumulated Deficit	(114,618)	(119,646)	(126,867)	(129,904)	(84,668)	(107,506)	(121,854)	(121,814)	(129,701)	(130,885)
Total stockholders equity		17,158	12,656	9,966	8,286	7,415	8,361	9,298	9,680	9,873	10,087
Total liabilities and stockholder equity		20,848	16,749	15,557	13,619	14,583	15,034	15,628	15,871	15,666	15,982

HISTORICAL STOCK PRICE



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