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Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Approaching an Exciting Inflection Point

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 (11/04/25)	$0.80
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 its 3Q 2025 earnings results that showed good cost discipline, while giving a timeline for the path to commercialization. The company is at an inflection point, and we are optimistic about the direction the company will take.

SUMMARY DATA

52-Week High	**$2.30**
52-Week Low	**$0.68**
One-Year Return (%)	**-64.44**
Beta	**0.16**
Average Daily Volume (sh)	**552,899**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$14**
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, Lomecel-B (also known as 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 Lomecel-B 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.

Before we get into the details of the HLHS program, which are very exciting, a quick look at the company's 3Q2025 earnings results is instructive. The company released its 3Q2025 earnings results that showed a $0.39 per share loss and revenues of $94,000. During the investor call following the release, management noted that it is looking to move the manufacturing of the product to a third party in order to prepare for commercialization. Additionally, the company announced that it expects to submit its BLA for full approval in 2027 in order to extend the cash runway and optimize cash usage. We are pleased to see the cost discipline we're seeing and management's planning for commercialization through the best use of funds.

Digging more into HLHS, it 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 Lomecel-B 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, Lomecel-B 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 Lomecel-B 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 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 Lomecel-B 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 Lomecel-B 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.

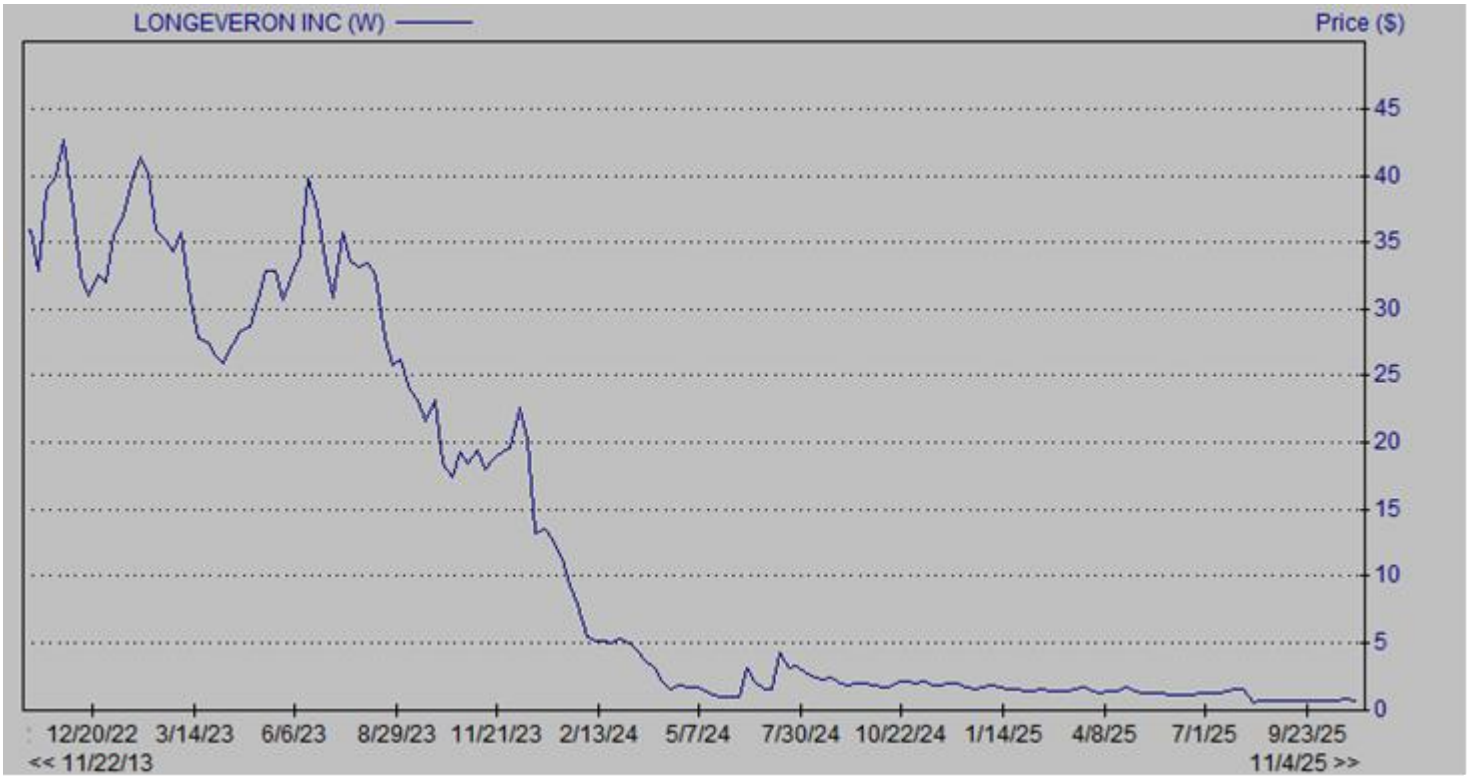
PROJECTED INCOME STATEMENT & BALANCE SHEET

Longeveron Income Statement and Balance Sheet

(US $ in thousands, except per share data)

		1Q2024A	2Q2024A	3Q2024A	4Q2024A	1Q2025A	2Q2025A	3Q2025A	4Q2025E	2026E	2027E
Revenues											
	Sales	0	0	0	0	0	0	0	0	0	1000
	Grant Revenue	0	0	0	0	0	0	0	0	0	0
	Clinical Trial Revenue	515	287	210	390	259	298	100	102	408	416
	Contract Manufacture Revenue	33	181	563	213	122	18	37	38	151	154
Total Revenues		548	468	773	603	381	316	137	140	559	1,570
	Cost of Revenues	219	124	91	74	106	170	12	77	307	864
Gross Profit		329	344	682	529	275	146	125	63	252	707
Operating Expenses											
	General and administrative	2,200	2,122	3,125	2,822	2,941	2,589	3,583	3,690	14,762	15,205
	Research and development	2,219	1,722	2,206	1,990	2,515	2,954	3,852	4,237	16,949	17,457
	Selling and marketing	0	0	0	0	0	0	0	0	0	0
Total operating expenses		4,419	3,844	5,331	4,812	5,456	5,543	7,435	7,928	31,711	32,662
Loss from operations		(4,090)	(3,500)	(4,649)	(4,283)	(5,181)	(5,397)	(7,310)	(7,865)	(31,459)	(31,956)
Other income and (expenses)											
	Interest expense	0	0	0	0	0	0	0	0	0	0
	Other income, net	32	87	230	200	170	369	89	90	500	550
Total other income and (expenses), net		32	87	230	200	170	369	89	90	500	550
Net loss		(4,058)	(3,413)	(4,419)	(4,083)	(5,011)	(5,028)	(7,221)	(7,775)	(30,959)	(31,406)
Dividend attributable to warrant inducement		0	(8,501)	(149)	0	0	0	0	0	0	0
Basic and diluted loss per share		$ (1.61)	$ (1.83)	$ (0.34)	$ (0.43)	$ (0.34)	$ (0.33)	$ (0.39)	$ (0.42)	$ (1.65)	$ (1.66)
Basic and diluted wtd avg common shares		2,516,587	6,509,881	13,627,793	9,411,164	14,950,734	15,013,072	18,373,198	18,556,930	18,742,499	18,929,924
Assets											
Current Assets:											
	Cash	1,940	12,375	22,778	19,232	14,327	10,334	9,244	7,395	5,916	4,733
	Securities and other current assets	1,817	1,035	989	392	948	935	1,096	1,129	1,163	1,198
Total Current Assets		3,757	13,410	23,767	19,624	15,275	11,269	10,340	8,524	7,079	5,931
Property, Plant and Equipment, net		2,348	2,371	2,622	2,449	2,288	2,258	2,122	2,016	1,915	1,819
Intangible assets, net		2,263	2,353	2,347	2,401	2,291	2,321	2,309	2,332	2,355	2,379
Other assets		1,329	1,259	1,173	1,084	994	901	786	747	709	674
Total Assets		9,697	19,393	29,909	25,558	20,848	16,749	15,557	13,619	12,059	10,803
Liabilities and stockholder equity											
Current liabilities:											
	Accounts Payable	1,467	600	887	99	367	700	1,080	1,102	1,124	1,146
	Accrued Expenses	2,401	1,605	1,479	1,820	1,647	1,905	3,173	3,332	3,498	3,673
	Current portion of lease	601	608	616	623	631	639	647	530	530	530
	Short-term note payable	-	-	-	-	-	-	-	-	-	-
	Current portion of loans	-	-	-	-	-	-	-	-	-	-
	Deferred Revenue	826	397	118	40	79	40	40	44	48	53
Total Current Liabilities		5,295	3,210	3,100	2,582	2,724	3,284	4,940	5,007	5,200	5,402
Long-term Liabilities:											
	Long-term loans	66	132	-	-	-	-	-	-	-	-
	Other Liabilities	-	-	199	265	-	308	315	-	-	-
	Lease Liability	1,295	1,140	983	824	966	501	336	326	316	307
Total long-term liabilities		1,361	1,272	1,182	1,089	966	809	651	326	316	307
Total liabilities		6,656	4,482	4,282	3,671	3,690	4,093	5,591	5,333	5,516	5,709
Stockholders Equity											
	Members equity	3	8	13	14	14	14	19	6	7	8
	Additional Paid-in capital	92,080	115,859	131,139	131,480	131,762	132,288	136,813	138,181	139,563	140,959
	Stock Subscription receivable	-	-	-	-	-	-	1	3	4	5
	Accumulated Deficit	(89,042)	(100,956)	(105,525)	(109,607)	(114,618)	(119,646)	(126,867)	(129,904)	(133,031)	(135,428)
Total stockholders equity		3,041	14,911	25,627	21,887	17,158	12,656	9,966	8,286	6,543	5,544
Total liabilities and stockholder equity		9,697	19,393	29,909	25,558	20,848	16,749	15,557	13,619	12,059	11,253

HISTORICAL STOCK PRICE



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