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Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Treatment Approved for Phase 2 Trial

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 $9.55 on LGVN using the discounted cash flow model.

Current Price (07/07/25)	$1.29
Valuation	**$9.55**

OUTLOOK

Longeveron is focusing on using its primary treatment, Lomecel-B, to fight a rare pediatric heart birth defect that devastates families but continues to receive good FDA news regarding its treatment for Alzheimer's Disease.

The company announced that its primary drug, laromestrocel, has been approved for a Phase 2 trial for the treatment of Pediatric Dilated Cardiomyopathy. This expands the potential market for treatment and provides hope for thousands of patients.

SUMMARY DATA

52-Week High	**$4.55**
52-Week Low	**$1.15**
One-Year Return (%)	**-37.68**
Beta	**0.21**
Average Daily Volume (sh)	**128,817**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$19**
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	0.4 E	0.4 E	0.4 E	1.6 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	-$0.36 E	-$0.38 E	-$0.40 E	-$1.48 E

Update

Longeveron is a company that should be getting more attention from investors for the treatments that could be coming to market in the near future. The next 12-18 months will prove to be critical for the company, and we urge investors to take a look at LGVN in advance of the upcoming potential catalysts. LGVN has made substantial progress with its signature treatment, Lomecel-B, also known as laromestrocel, in treating both HLHS and Alzheimer's Disease and we are looking forward to the year ahead when we expect to receive exciting news.

Investors got some of that exciting news recently, when the company announced that laromestrocel has been approved for a Phase 2 trial for an additional medical condition—pediatric dilated cardiomyopathy (DCM). DCM occurs when the muscles of one or more heart chambers become enlarged (dilated). This causes other chambers to work harder and can lead to congestive heart failure. According to the company, DCM is the common form of cardiomyopathy in children, with about 40% of them needing a heart transplant or dying within two years of being diagnosed. The company also noted that trial initiation is likely in the first half of 2026.

Obviously, this treatment could be a game changer, and we are more convinced of that following comments by the Associate Chair of Pediatrics and Director of the Powell Gene Therapy Center at the University of Florida. Dr. Barry Byrne stated, “Current treatment for DCM focuses on managing symptoms, improving heart function, and preventing complications rather than addressing the underlying cause or causes. Many therapeutic agents with known efficacy in adults lack the same evidence in children. Longeveron’s innovative stem cell therapy approach, with the possibility for stem cells to repair damaged heart tissue, is a potential groundbreaking development in the treatment of children with cardiovascular diseases.”

This follows news that the company has full enrollment in the pivotal Phase 2b clinical trial of laromestrocel for the treatment of Hypoplastic Left Heart Syndrome (HLHS). This marked a major milestone for the company. Due to the rare nature of the condition, finding patients eligible and willing to participate in the trial was a major challenge and now that it’s completed, the clock toward approval can start. Along with the enrollment announcement, company management outlined the expected timeline, with top-line results anticipated in 3Q2026, followed by the filing of a Biological License Application, provided the testing results are positive, which we fully expect. As a reminder, laromestrocel has been granted Orphan Drug designation, Fast Track designation, and Rare Pediatric Disease designation by the FDA.

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.

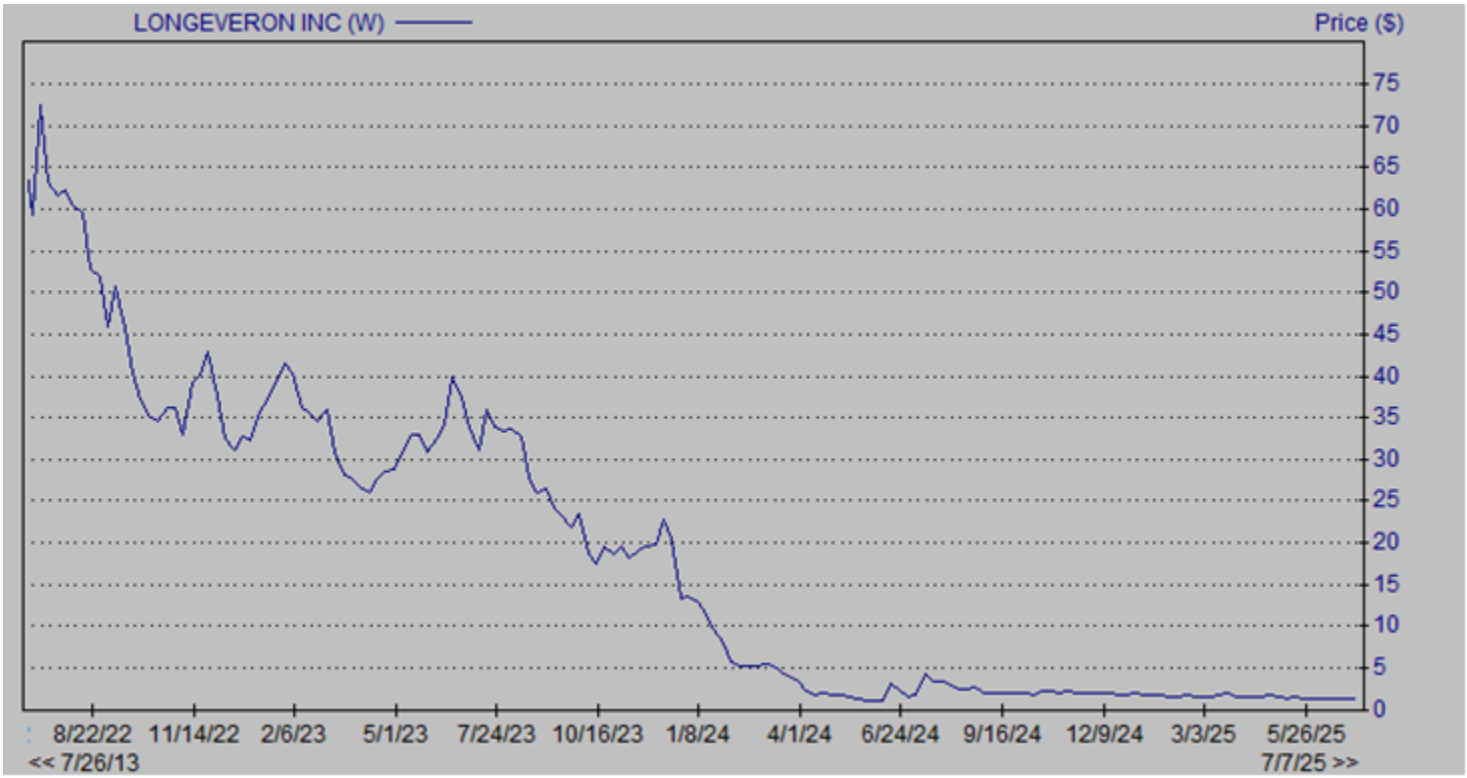
Summary

We continue to believe that Longeveron is an exciting clinical-stage company and investors aren't appropriately appreciating the game-changing potential Lomecel-B 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 Lomecel-B 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**	**2Q2025E**	**3Q2025E**	**4Q2025E**
Revenues									
	Grant Revenue	0	0	0	0	0	0	0	0
	Clinical Trial Revenue	515	287	210	390	259	264	269	275
	Contract Manufacture Revenue	33	181	563	213	122	124	127	129
Total Revenues		548	468	773	603	381	389	396	404
	Cost of Revenues	219	124	91	74	106	214	218	222
Gross Profit		329	344	682	529	275	175	178	182
Operating Expenses									
	General and administrative	2,200	2,122	3,125	2,822	2,941	3,029	3,120	3,214
	Research and development	2,219	1,722	2,206	1,990	2,515	2,767	3,043	3,347
	Selling and marketing	0	0	0	0	0	0	0	0
Total operating expenses		4,419	3,844	5,331	4,812	5,456	5,796	6,163	6,561
Loss from operations		(4,090)	(3,500)	(4,649)	(4,283)	(5,181)	(5,621)	(5,985)	(6,379)
Other income and (expenses)									
	Interest expense	0	0	0	0	0	0	0	0
	Other income, net	32	87	230	200	170	172	173	175
Total other income and (expenses), net		32	87	230	200	170	172	173	175
Net loss		(4,058)	(3,413)	(4,419)	(4,083)	(5,011)	(5,449)	(5,811)	(6,204)
Dividend attributable to warrant inducement		0	(8,501)	(149)	0	0	1	2	3
Basic and diluted loss per share		$ (1.61)	$ (1.83)	$ (0.34)	$ (0.43)	$ (0.34)	$ (0.36)	$ (0.38)	$ (0.40)
Basic and diluted wtd avg common shares		2,516,587	6,509,881	13,627,793	9,411,164	14,950,734	15,100,241	15,251,244	15,403,756
Assets									
Current Assets:									
	Cash	1,940	12,375	22,778	19,232	14,327	11,462	9,169	7,335
	Securities and other current assets	1,817	1,035	989	392	948	976	1,006	1,036
Total Current Assets		3,757	13,410	23,767	19,624	15,275	12,438	10,175	8,371
Property, Plant and Equipment, net		2,348	2,371	2,622	2,449	2,288	2,174	2,065	1,962
Intangible assets, net		2,263	2,353	2,347	2,401	2,291	2,314	2,337	2,360
Other assets		1,329	1,259	1,173	1,084	994	944	897	852
Total Assets		9,697	19,393	29,909	25,558	20,848	17,870	15,474	13,546
Liabilities and stockholder equity									
Current liabilities:									
	Accounts Payable	1,467	600	887	99	367	374	382	389
	Accrued Expenses	2,401	1,605	1,479	1,820	1,647	1,729	1,816	1,907
	Current portion of lease	601	608	616	623	631	530	530	530
	Short-term note payable	-	-	-	-	-	-	-	-
	Current portion of loans	-	-	-	-	-	-	-	-
	Deferred Revenue	826	397	118	40	79	87	96	105
Total Current Liabilities		5,295	3,210	3,100	2,582	2,724	2,721	2,823	2,931
Long-term Liabilities:									
	Long-term loans	66	132	-	-	-	-	-	-
	Other Liabilities	-	-	199	265	-	-	-	-
	Lease Liability	1,295	1,140	983	824	966	937	909	882
Total long-term liabilities		1,361	1,272	1,182	1,089	966	937	909	882
Total liabilities		6,656	4,482	4,282	3,671	3,690	3,658	3,732	3,813
Stockholders Equity									
	Members equity	3	8	13	14	14	4	5	6
	Additional Paid-in capital	92,080	115,859	131,139	131,480	131,762	133,080	134,410	135,755
	Stock Subscription receivable	-	-	-	-	-	1	2	3
	Accumulated Deficit	(89,042)	(100,956)	(105,525)	(109,607)	(114,618)	(118,872)	(122,676)	(126,031)
Total stockholders equity		3,041	14,911	25,627	21,887	17,158	14,212	11,742	9,733
Total liabilities and stockholder equity		9,697	19,393	29,909	25,558	20,848	17,870	15,474	13,546

HISTORICAL STOCK PRICE



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