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Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Positive Trial Update and First Contract

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 $15.10 on LGVN using the discounted cash flow model.

Current Price (06/11/24)	$0.82
Valuation	**$15.10**

OUTLOOK

Longeveron is focusing on using its primary treatment, Lomecel-B, to fight a rare pediatric heart birth defect that devastates families.

The company announced the completion of an encouraging meeting with investigators involved in the ongoing trial of Lomecel-B for the treatment of HLHS. Additionally, the LGVN announced it has signed its first contract for the use of its state-of-the-art manufacturing facility.

SUMMARY DATA

52-Week High	**$40.00**
52-Week Low	**$0.82**
One-Year Return (%)	**-97.83**
Beta	**0.33**
Average Daily Volume (sh)	**382,546**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**19**
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	0.6 E	0.6 E	0.6 E	2.3 E
2025	0.6 E	0.6 E	0.6 E	0.7 E	2.5 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	-$1.55 E	-$1.46 E	-$1.28 E	-$5.90 E
2025	-$1.55 E	-$1.60 E	-$1.60 E	-$1.71 E	-$6.46 E

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Update

The recent string of positive developments for Longeveron continues and we are becoming more encouraged that the company will be able to help parents desperate for a treatment for an often-fatal condition. Hypoplastic Left Heart Syndrome (HLHS) is a rare and life-threatening congenital heart defect affecting approximately 1,000 babies per year according to the company. Infants born with HLHS have an underdeveloped or absent left ventricle. Current standard-of-care is comprised of three reconstructive heart surgeries (Stage 1 – 3) to reconfigure the right ventricle to provide all cardiac output. These three surgeries must be performed within the first five years of life. The Stage 1 surgery (the Norwood procedure) is conducted within 2 weeks of birth and the Stage 2 (the Glenn procedure) is typically conducted by 4-5 months of age. A Stage 3 surgery (the Fontan procedure) is typically performed when the children are 4-5 years of age. Without surgical treatment, the condition is always fatal, and even with reconstructive surgical reconstruction, patients often die or require heart transplantation by 15 years of age.

The company believes that Lomecel-B can improve these patients' outcomes and is currently involved in a Phase 2b clinical trial in an attempt to verify this belief. This trial is to evaluate the safety and efficacy of intramyocardial injection of Lomecel-B in infants with HLHS undergoing the Glenn Procedure.

Recently, the company gave an update on a meeting with investigators involved with the study that we view as extremely encouraging. The company described it as successful, but we believe a quote from a principal investigator in the study says it better than we could. Dr. Ram Kumar Subramanyan, division chief of Pediatric Cardiothoracic Surgery and Children's Nebraska said, "While we have made significant advances in diagnosing HLHS before a baby is born, we don't yet know the cause, and current HLHS treatment requires infants to undergo a complex three-stage surgical reconstruction over the first 3-4 years of their life. Even with this comprehensive treatment, only 50% to 60% of infants survive to adolescence due to right ventricular failure. There is clearly an important unmet medical need to improve right ventricular function in these infants to positively impact both short- and long-term patient outcomes. Lomecel-B's Phase 1 clinical data is highly encouraging and suggests it has the potential to be a new, additive treatment option for physicians and their patients dealing with HLHS. The community is very much looking forward to the results of ELPIS II (the Stage 2b trial)."

Following the meeting, company management confirmed that Longeveron "remains on track to complete enrollment of the clinical trial by the end of the year."

As a reminder and another reason to like LGVN, Lomecel-B for HLHS has received Fast Track, Rare Pediatric Disease, and Orphan Drug Designations from the FDA. In the earnings call, Mr. Hashad noted that enrollment in the trial should be completed by the end of the year, and also reminded investors that the Rare Pediatric Disease designation is a valuable one and can be sold should the company choose to do so—with current prices hovering around the $100 million mark.

Additionally, management recently outlined the company's plan to add to revenue generated while going through the FDA approval process. The company owns a world-class manufacturing facility that has excess capacity at the current time. As part of this plan, Longeveron announced the signing of its first contract to use its facility in a deal with Secretome Therapeutics. We are every encouraged by the addition of this revenue stream, which the company estimates could reach $4-5 million annually, which will help to fund the important work the company is undergoing.

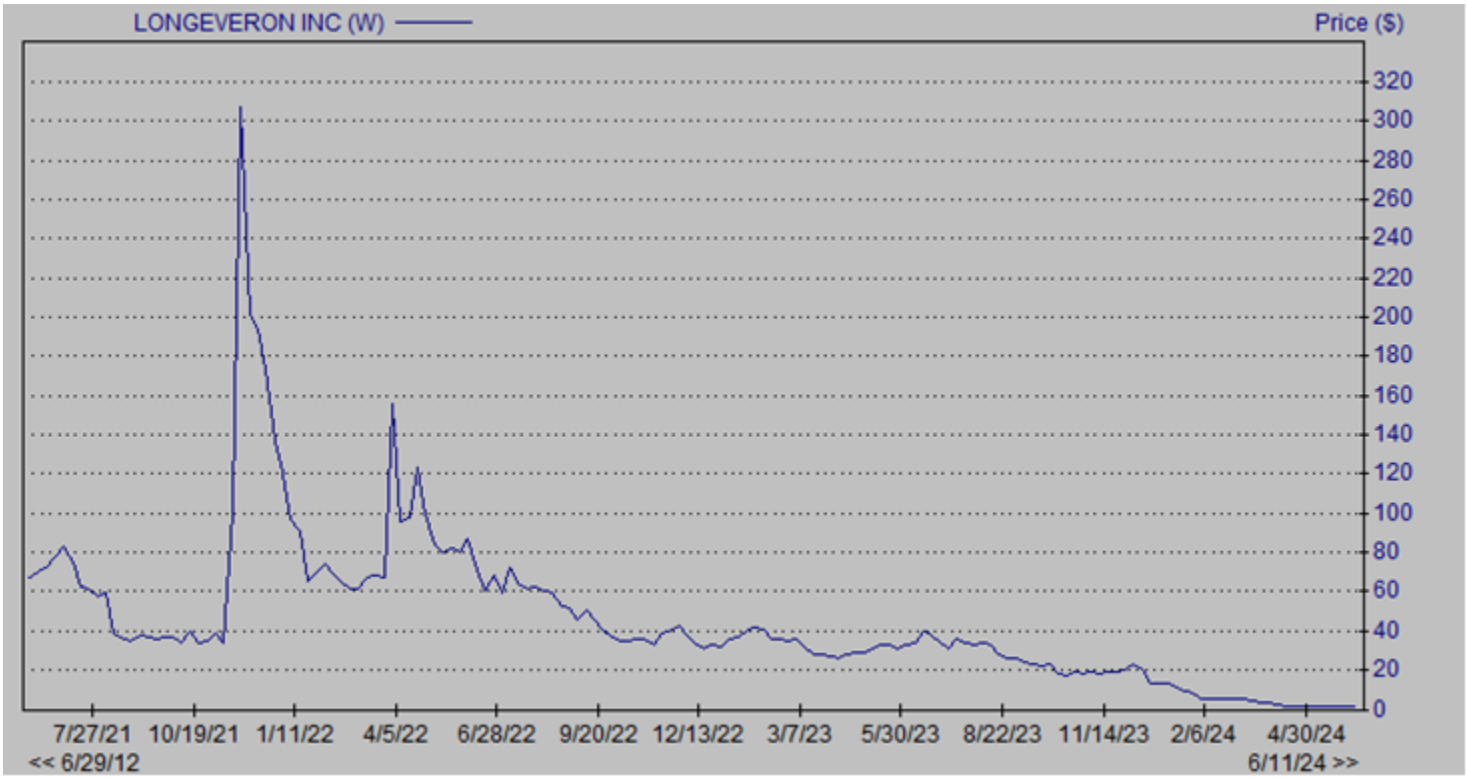
Summary

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 Lomecel-B will ultimately have a substantial impact on the health situations of thousands of patients. We encourage investors to take a close look at Longeveron and the company's prospects and potential, which we believe to be quite positive.

PROJECTED INCOME STATEMENT & BALANCE SHEET

Longeveron Income Statement and Balance Sheet							
(in thousands, except per share data)							
		2023A	**1Q2024E**	**2Q2024E**	**3Q2024E**	**4Q2024E**	**2025E**
Revenues							
	Grant Revenue	41	0	0	0	0	0
	Clinical Trial Revenue	668	515	525	536	547	2186
	Contract Manufacture Revenue	0	33	75	75	75	300
Total Revenues		709	548	600	611	622	2,486
	Cost of Revenues	488	219	330	336	342	1367
Gross Profit		221	329	270	275	280	1,119
Operating Expenses							
	General and administrative	11,401	2,200	1,980	1,782	1,604	11,550
	Research and development	9,066	2,219	2,241	2,264	2,286	9,145
	Selling and marketing	783	0	143	280	110	175
Total operating expenses		21,250	4,419	4,364	4,326	4,000	20,870
Loss from operations		(21,029)	(4,090)	(4,094)	(4,051)	(3,720)	(19,751)
Other income and (expenses)							
	Interest expense	0	0	0	0	0	0
	Other income, net	(384)	32	0	0	0	0
Total other income and (expenses), net		(384)	32	0	0	0	0
Net loss		(21,413)	(4,058)	(4,094)	(4,051)	(3,720)	(19,751)
Dividend attributable to warrant		(798)	0	0	0	0	0
Basic and diluted loss per share		$ (1.02)	$ (1.61)	$ (1.55)	$ (1.46)	$ (1.28)	$ (6.46)
Basic and diluted wtd avg common shares		21,734,901	2,516,587	2,642,416	2,774,537	2,913,264	3,058,927
Assets							
Current Assets:							
	Cash	4,949	1,940	5,001,552	4,001,242	3,200,993	2,560,795
	Securities and other current assets	899	1,817	1,872	1,928	1,985	2,045
Total Current Assets		5,848	3,757	5,003,424	4,003,169	3,202,979	2,562,840
Property, Plant and Equipment, net		2,529	2,348	2,717	2,544	2,403	2,282
Intangible assets, net		2,287	2,263	2,482	2,539	2,310	2,333
Other assets		1,414	1,329	1,602	1,498	1,273	1,209
Total Assets		12,078	9,697	5,010,225	4,009,750	3,208,964	2,568,664
Liabilities and stockholder equity							
Current liabilities:							
	Accounts Payable	638	1,467	1,496	1,526	1,557	1,588
	Accrued Expenses	2,152	2,401	2,521	2,647	2,779	2,918
	Current portion of lease	593	601	578	586	520	530
	Short-term note payable	-	-	-	-	-	-
	Current portion of loans	-	-	-	-	-	-
	Deferred Revenue	506	826	496	506	202	222
Total Current Liabilities		3,889	5,295	5,091	5,265	5,058	5,259
Long-term Liabilities:							
	Long-term loans	-	66	-	-	-	-
	Lease Liability	1,448	1,295	1,748	1,599	1,405	1,362
Total long-term liabilities		1,448	1,361	1,748	1,599	1,405	1,362
Total liabilities		5,337	6,656	6,839	6,864	6,463	6,621
Stockholders Equity							
	Members equity	25	3	3	3	3	3
	Additional Paid-in capital	91,800	92,080	5,084,005	4,084,694	3,285,686	2,647,717
	Stock Subscription receivable	(100)	-	-	-	-	-
	Accumulated Deficit	(84,984)	(89,042)	(80,623)	(81,811)	(83,333)	(88,024)
Total stockholders equity		6,741	3,041	5,003,385	4,002,886	3,202,356	2,559,696
Total liabilities and stockholder equity		12,078	9,697	5,010,224	4,009,750	3,208,818	2,566,317

HISTORICAL STOCK PRICE



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