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Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Focus and Cost Controls Improve Outlook

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 $15.15 on LGVN using the discounted cash flow model.

Current Price (05/14/24)	$1.39
Valuation	**$15.15**

OUTLOOK

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

Under new leadership, the company has focused on specific objectives, cut costs, and looked to maximize revenue opportunities. We believe the company is on a better and more sustainable track and are excited about ongoing developments and the just released 1Q2024 earnings report reinforces that view.

SUMMARY DATA

52-Week High	**$40.00**
52-Week Low	**$1.67**
One-Year Return (%)	**-95.80**
Beta	**0.51**
Average Daily Volume (sh)	**3,888,117**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**24**
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

Longeveron has been under the leadership of a new CEO for just over a year, and we continue to be impressed with Mr. Hashad's decisions, vision, and focus. We have been telling investors about the great potential we've seen in early testing for the company's signature treatment-Lomecel-B. However, as with many clinical-stage companies, we were concerned the company may be spreading its resources too thin. We understood that the multiple potential uses for Lomecel-B likely warranted multiple lines of testing but choosing that path can prove costly and has the potential to derail the company's potential.

Since Mr. Hashad has taken the helm, however, the company has focused on getting Lomecel-B approved for use for the treatment of hypoplastic left heart syndrome (HLHS), a stance which was reiterated in the conference call following the 1Q2024 earnings release. 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 the results released earlier lend support to those hopes. The company shared data that showed 100% of the 10 patients who participated in the trial survived and remained transplant-free for up to 5 years of age after receiving Lomecel-B during their Stage 2 surgery. According to the company, historical data has shown that children with HLHS have approximately 20% mortality by 5 years. This continues the positive results we are seeing out of trials of Lomecel-B and we are excited that the company is currently enrolling patients in the Phase 2b trial, which will involve 38 patients. This trial will be to evaluate the safety and efficacy of intramyocardial injection of Lomecel-B in infants with HLHS undergoing the Glenn Procedure. 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.

During the conference call, management also 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. Longeveron has started to lease out space in that facility and will continue to do so for the foreseeable future, providing another income stream to the company.

Also, although the company has put the testing for Lomecel-B as a treatment for Aging Frailty, participants in the Bahamas Trial urged the company to allow them to continue the testing at their own expense-and the company agreed. This allows a cost-neutral trial, which benefits patients and provides the company with valuable information—the proverbial win-win.

The 1Q2024 earnings release also revealed that the company has cut operating expenses by 8% y/y, confirming our belief that the new management was making tough and important decisions. Additionally, we wrote recently about the cash raise that the company completed in April, which put them in a much better financial position to continue the path toward approval.

Lastly, although Longeveron has put the following program on a back burner as it seeks a strategic partner, the company recently announced that its CLEAR MIND Phase 2a trial evaluating Lomecel-B in mild Alzheimer's Disease has been accepted for a Featured Research Session Oral Presentation at the 2024 Alzheimer's Association International Conference. As a reminder, those results include:

- The primary endpoint of the study of safety was met across all study groups.
- The company also reported that Lomecel-B improved cognitive function, while caregivers documented improved quality of life in Lomecel-B treated patients with Alzheimer’s disease. Additionally, the company noted that MRI Biomarker data showed that “Lomecel-B countered loss of brain volume in multiple areas associated with Alzheimer's disease.”

This announcement encourages our optimism about the potential for Lomecel-B to positively impact those suffering from Alzheimer's and raises the possibility of finding a strategic partner that will help Longeveron bring this badly needed treatment to market.

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. Our price target is what we believe to be a somewhat conservative $15.15 per share, which is well above the recent trading range as we believe investors aren’t appreciating the potential of Lomecel-B’s commercialization and believe patient investors will be rewarded.

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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