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Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Positive Test Results for Alzheimer Drug

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 $14.30 on LGVN using the discounted cash flow model.

Current Price (10/04/23)	$2.51
Valuation	**$14.30**

OUTLOOK

Longeveron announced top-line results from its trial of Lomecel-B for the treatment of Alzheimer's disease.

The results met the primary endpoint of safety and also showed positive cognitive results compared to a placebo. These results reinforce our belief that Lomecel-B has the potential to be a game-changing drug for several serious conditions.

SUMMARY DATA

52-Week High	**$4.36**
52-Week Low	**$2.15**
One-Year Return (%)	**-35.15**
Beta	**0.74**
Average Daily Volume (sh)	**73,059**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$53**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**75**
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)
2021	0.4 A	0.5 A	0.2 A	0.2 A	1.4 A
2022	0.4 A	0.5 A	0.3 A	0.1 A	1.2 A
2023	0.3 A	0.2 A	0.4 E	0.3 E	1.2 E
2024	0.3 E	0.3 E	0.4 E	0.3 E	1.3 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.18 A	-$0.26 A	-$0.25 A	-$0.20 A	-$0.90 A
2022	-$0.17 A	-$0.27 A	-$0.25 A	-$0.21 A	-$0.90 A
2023	-$0.22 A	-$0.27 A	-$0.24 E	-$0.23 E	-$0.95 E
2024	-$0.18 E	-$0.19 E	-$0.16 E	-$0.22 E	-$0.75 E

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Updates

Longeveron announced results from its Phase 2a trial of its signature drug, Lomecel-B. The primary endpoint of the study of safety was met across all study groups. While this result is unabashedly positive, it was the observations of potential efficacy in treating Alzheimer's that we were most interested in.

The company reported that Lomecel-B demonstrated statistically significant slowing of disease progression in comparison to the placebo. Longeveron also noted that the significance was met for the secondary endpoint Composite Alzheimer's Disease Score—or CADS—for Lomecel-B.

This continues the string of recent positive data released by the company regarding the progression of Lomecel-B and we are looking forward to that continuing later in the month when management expects to release additional biomarker data.

As mentioned, the company also recently announced that it has exceeded the 50% threshold for the Phase 2 trial of Lomecel-B in hypoplastic left heart syndrome (HLHS). This added to the previous announcement by Longeveron regarding long-term follow-up data from the company's trial of Lomecel-B for patients with HLHS. As a quick reminder, 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 is hoping that Lomecel-B can improve on 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 2a 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.

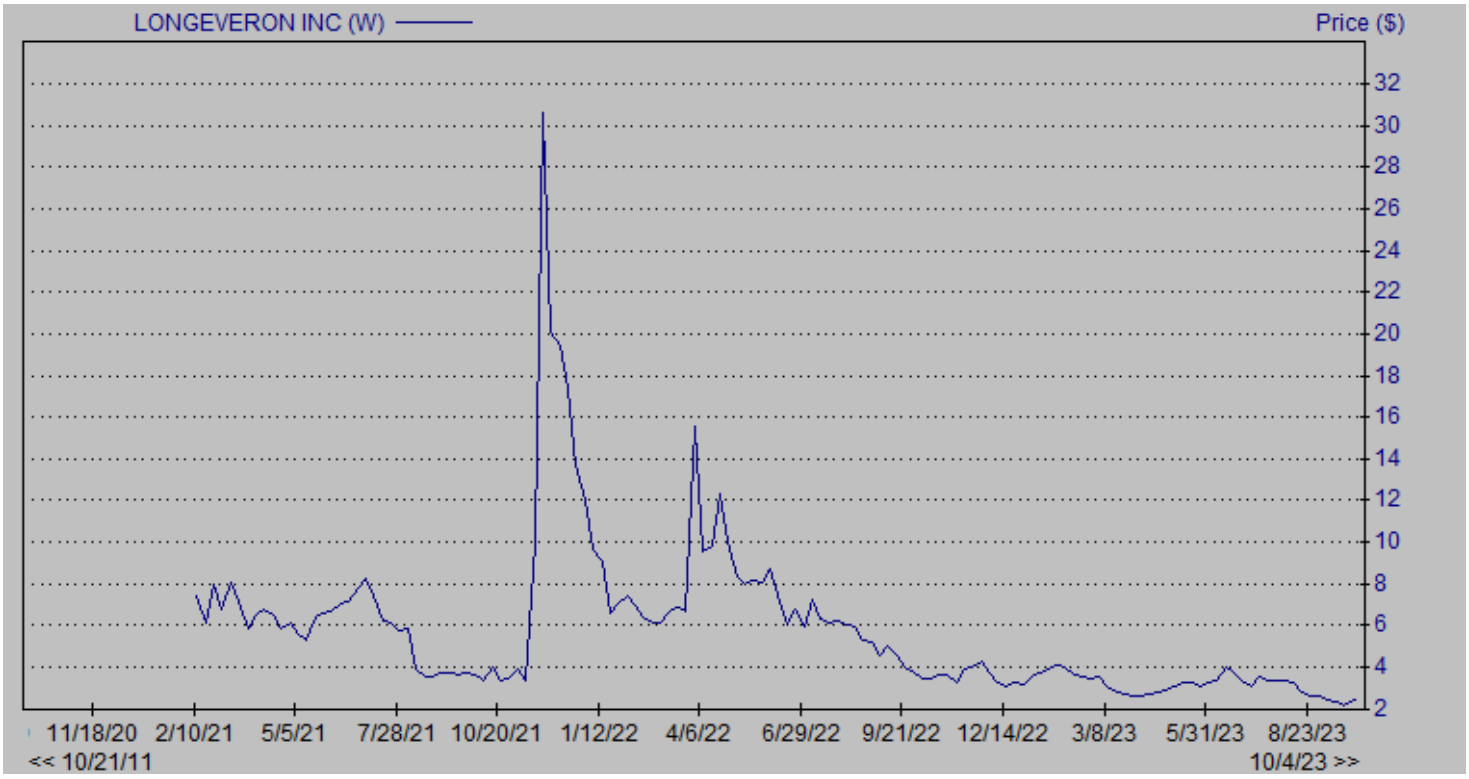
Summary

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 persistent and competent management, that appears to be continuing with several new management members, and solid science the company is moving consistently forward, and we believe that 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 $14.30 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.

INCOME STATEMENT AND BALANCE SHEET

Longeveron Income Statement and Balance Sheet							
(in thousands, except per share data)							
		4Q2022A	**1Q2023A**	**2Q2023A**	**3Q2023E**	**4Q2023E**	**2024E**
Revenues							
	Grant Revenue	41	41	217	210	200	875
	Clinical Trial Revenue	80	238	0	55	90	410
	Contract Revenue	0	0	0	0	0	0
Total Revenues		121	279	217	265	290	1,285
	Cost of Revenues	175	203	124	173	177	179
Gross Profit		(54)	76	93	92	113	1,106
Operating Expenses							
	General and administrative	1,637	1,855	3,375	2,074	2,095	11,550
	Research and development	3,263	2,780	2,287	2,960	2,990	5,825
	Selling and marketing	285	157	143	245	110	175
Total operating expenses		5,185	4,792	5,805	5,279	5,194	17,550
Loss from operations		(5,239)	(4,716)	(5,712)	(5,187)	(5,081)	(16,444)
Other income and (expenses)							
	Interest expense	0	69	0	0	0	0
	Other income, net	783	0	80	(57)	0	0
Total other income and (expenses), net		783	69	80	(57)	0	0
Net loss		(4,456)	(4,647)	(5,632)	(5,244)	(5,081)	(16,444)
Basic and diluted loss per share		$ (0.21)	$ (0.22)	$ (0.27)	$ (0.25)	$ (0.24)	$ (0.76)
Basic and diluted wtd avg common shares		21,017,885	21,033,610	21,105,420	21,316,474	21,529,639	21,744,935
Assets							
Current Assets:							
	Cash	10,503	4,984	2,747	13,574	25,576	25,692
	Short-term investments	9,155	8,693	7,545	8,742	9,430	9,713
Total Current Assets		19,658	13,677	10,292	22,316	35,006	35,405
Property, Plant and Equipment, net		2,949	2,810	2,717	3,064	2,802	2,661
Intangible assets, net		2,409	2,425	2,482	2,373	2,433	2,457
Other assets		2,397	2,896	1,602	2,762	2,157	2,049
Total Assets		27,413	21,808	17,093	30,515	42,398	42,573
Liabilities and stockholder equity							
Current liabilities:		Details estimated	Details estimated				
	Accounts Payable	975	1,000	1,700	860	727	807
	Accrued Expenses	1,150	900	1,308	947	625	875
	Current portion of lease	530	520	578	517	520	530
	Short-term note payable	-	-	-	-	-	-
	Current portion of loans	5	5	-	5	5	5
	Deferred Revenue	202	202	496	202	202	222
Total Current Liabilities		2,862	2,627	4,082	2,531	2,079	2,439
Long-term Liabilities:							
	Long-term loans	648	271	-	145	648	648
	Lease Liability	3,400	2,592	1,748	3,214	3,298	3,199
Total long-term liabilities		4,048	2,863	1,748	3,359	3,946	3,847
Total liabilities		6,910	5,490	5,830	5,890	6,025	6,286
Stockholders Equity							
	Members equity	19	19	21	19	19	19
	Additional Paid-in capital	50,412	50,412	84,729	55,696	60,766	72,240
	Stock Subscription receivable	(100)	(100)	(100)	(100)	(100)	(100)
	Accumulated Deficit	(29,828)	(34,013)	(73,387)	(30,990)	(24,312)	(35,873)
Total stockholders equity		20,503	16,318	11,263	24,625	36,373	36,287
Total liabilities and stockholder equity		27,413	21,808	17,093	30,515	42,398	42,573

HISTORICAL STOCK PRICE



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