July 10, 2024

Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: FDA Grants Alzheimer's Candidate Important Designation

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 $10.75 on LGVN using the discounted cash flow model.

Current Price (07/09/24)	$2.87
Valuation	**$10.75**

OUTLOOK

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

The company announced that Lomecel B has been granted the Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA, which we believe improves prospects for the company through development and/or partnerships.

SUMMARY DATA

52-Week High	**$35.90**
52-Week Low	**$0.82**
One-Year Return (%)	**-91.25**
Beta	**0.43**
Average Daily Volume (sh)	**21,794,588**
Shares Outstanding (mil)	**46**
Market Capitalization ($mil)	**$18**
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	-$0.94 E	-$0.89 E	-$0.78 E	-$4.22 E
2025	-$1.00 E	-$0.98 E	-$0.97 E	-$0.98 E	-$3.93 E

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Update

Longeveron announced that its primary treatment, Lomecel-B, has been granted Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA for the treatment of Alzheimer's Disease. This adds to the designations received from the FDA that include Orphan Drug Designation, Fast Track Designation, and Rare Pediatric Disease Designation for Lomecel-B the treatment of hypoplastic left heart syndrome (HLHS), which we've written extensively about before.

The RMAT designation is a fairly recent one, created when the 21st Century Cures Act was passed. The designation is designed to expedite the drug development and review processes for promising pipeline regenerative medicine products, including cell therapies, which Lomecel-B is. A regenerative medicine therapy is eligible for RMAT designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or therapy has the potential to address unmet medical needs for such disease or condition. This new designation is similar to the longer-standing Breakthrough Therapy designation and provides the benefits of intensive FDA guidance on efficient drug development It includes the ability for early interactions with FDA to discuss surrogate or intermediate endpoints, potential ways to support accelerated approval and satisfy post-approval requirements, and potential priority review of the biologics license application (BLA) if Priority Review designation is granted following BLA submission.

Alzheimer's Disease is a devastating disease millions of people and their families, with the Alzheimer's Association estimating nearly seven million people suffering from the condition at the present time, with that number expected to grow substantially in the coming years. There have been several high-profile FDA approvals for treatments of Alzheimer's at various stages and with limited impacts. That's not to denigrate any existing treatment but point out the even the companies with the approved drugs believe there is much more work to do. The clinical results for Lomecel-B are detailed below and we have believed the results were very encouraging and are pleased to see the FDA recognize the potential the treatment has.

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 from the FDA about the RMAT designation further 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. As a result of our view that there is an increased possibility of a partnership or other financial transaction involving a major pharmaceutical company, we are boosting the valuation of LGVN to $10.75 per share.

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. Despite the raising of our price target, we continue to believe our valuation is conservative given 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							
(in thousands, except per share data)							
		2023A	**1Q2024A**	**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)	$ (0.94)	$ (0.89)	$ (0.78)	$ (3.93)
Basic and diluted wtd avg common shares		21,734,901	2,516,587	4,340,307	4,557,323	4,785,189	5,024,448
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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