October 28, 2024

Zacks Small-Cap Research

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Longeveron Inc (LGVN-NASDAQ)

LGVN: Heart Study Results Highlight Conference Presentation

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 $9.50 on LGVN using the discounted cash flow model.

Current Price (10/25/24)	$2.21
Valuation	**$9.50**

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 positive results from its Phase 1 study of Lomecel-B in the treatment of a devastating heart condition impacting children known as HLHS.

SUMMARY DATA

52-Week High	**$23.70**
52-Week Low	**$0.82**
One-Year Return (%)	**-88.12**
Beta	**0.36**
Average Daily Volume (sh)	**419,741**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$32**
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	0.5 A	0.4 E	0.4 E	1.8 E
2025	0.4 E	0.3 E	0.4 E	0.4 E	1.5 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	-$1.83 A	-$0.55 E	-$0.48 E	-$4.47 E
2025	-$0.61 E	-$0.60 E	-$0.60 E	-$0.59 E	-$2.40 E

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Update

Longeveron is a company that should be getting more attention from investors. LGVN has made substantial progress with its signature treatment, Lomecel-B, in treating both HLHS and Alzheimer's Disease and we suggest investors take a look at this stock before more good news comes out—such as what happened recently. The company announced follow up results of its Phase 1 trial of Lomecel-B for the treatment of HLHS (Hypoplastic Left Heart Syndrome). The results were very impressive and have the potential to give hope to parents of children with this devastating disease.

In order to understand how important these results are, investors need to understand how devastating HLHS can be. HLHS is a rare pediatric congenital heart birth defect in which the left ventricle (one of the pumping chambers of the heart) is either severely underdeveloped or missing. It is a devastating diagnosis for families with only 20-60% of babies with HLHS surviving their first year of life according to data compiled by the Cleveland Clinic.

Because of the rarity of the disease, designing studies can be difficult due to the limited number of potential patients. Additionally, part of how Lomecel-B's effectiveness will be evaluated will be how the test subjects progress as time goes on. It's those longer-term results that the company addressed at the Congenital Heart Surgeons' Society meeting, with the five-year follow-on results available. ELPIS I, as the Phase 1 study was called, was an open-label clinical trial designed to evaluate the safety of Lomecel-B™ in patients with HLHS. Patients underwent the Glenn Procedure (an open-heart surgery) at approximately 4-5 months of age. The results from the ELPIS I trial, which were previously reported, showed that the study met its primary safety endpoint and that all patients were alive, transplant-free, and maintained their expected rate of growth one year after treatment.

To assess long-term survival benefits, all ELPIS I patients (7 males, and 3 females) were followed for five years post-Glenn surgery and treatment with Lomecel-B to evaluate overall survival and transplant-free survival. Outcomes were compared with long-term historical data from patients in the Single Ventricle Reconstruction (SVR) Trial receiving the same shunt type at Stage I (Norwood) operation and underwent Glenn procedures. Key findings reported by the company include:

- 5-year post-Glenn procedure Kaplan-Meier survival was 100% in patients treated with Lomecel-B in ELPIS I, with none requiring heart transplant. This compared to 83% transplant-free survival in the SVR trial through 5 years post-Glenn surgery, and a 5.2% heart transplantation rate.
- No Major Adverse Cardiovascular Events (MACE) were reported during the study.
- No Lomecel-B related safety issues were reported.
- According to the company, these findings support the use of Lomecel-B as a potential adjunct to HLHS reconstruction surgery to improve transplant-free survival.

These results are very encouraging and support what we've been writing about—that LGVN is making great strides and has the potential to impact patients experiencing difficult diseases such as HLHS and Alzheimer's Disease, which we've highlighted in previous reports. We are looking forward to seeing results from the currently ongoing Phase 2 trial, known as ELPIS II. According to the company, ELPIS II is on-going and enrolling 38 pediatric patients at twelve premiere infant and children's treatment institutions across the country. The clinical trial is being conducted in collaboration with the National Heart, Lung, and Blood Institute (NHLBI) through grants from the National Institutes of Health (NIH).

As a reminder, FDA has granted Lomecel-B Orphan Drug designation, Fast Track designation, and Rare Pediatric Disease designation, which allow greater access to the agency during Lomecel-B's development for HLHS.

As a result of these positive long-term results and the increasing likelihood in our view that Longeveron has the potential to attract the attention of major pharmaceutical companies, we are slightly boosting our price target for LGVN.

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 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.

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