MAXIM GROUP

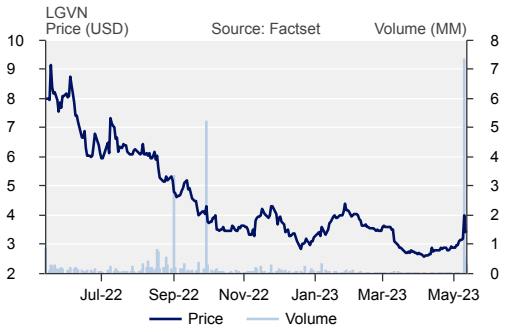
Equity Research
Company Update

Biotechnology

LGVN – NASDAQ	May 12, 2023
Intraday Price 5/12/23	**$3.31**
Rating:	Buy
12-Month Target Price:	$14.00
52-Week Range:	$2.50 - $9.34
Market Cap (M):	$20.4
Shares O/S (M):	6.2
Float:	73.5%
Avg. Daily Volume (000):	149.7
Debt (M):	$0.0
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Expenses ('000)

	2022A	2023E	2024E
1Q	3,764	4,995A	6,246
2Q	4,687	5,032	6,517
3Q	5,452	5,283	7,060
4Q	5,362	5,547	7,332
CY	19,265	20,597	27,154
Prior	—	20,394	27,104



Michael Okunewitch
(212) 895-3579
mokunewitch@maximgrp.com

Jason McCarthy, Ph.D.
(212) 895-3556
jmccarthy@maximgrp.com

Longeveron Inc.

Buy

1Q23 Results & Outlook: Progress Continues with Clinical Studies Ongoing Across HLHS, Frailty, and Alzheimer's

Summary

- This morning, Longeveron reported 1Q23 results with a net loss of ($4.6M) and ended the period with $13.7M in cash on the balance sheet. The company expects to have cash runway into 2Q24.
- The P2a ELPIS II trial in hypoplastic left heart syndrome (HLHS) continues to enroll across 7 sites, with one additional site planned.
- On 5/9/23, long-term follow-up data from the ELPIS I trial was announced, which demonstrated 100% survival (N=10) at up to five years post-administration vs. 20% mortality at five years for historical control (see note, **LINK**).
- In aging frailty, the P2 study is ongoing in Japan, which dosed the first patient on 4/19/23 (see note, **LINK**). For the Alzheimer's program, with enrollment complete in its P2a trial, top-line data is expected by YE23.

Details

ELPIS II study in HLHS. The ELPIS II study is a randomized, double-blind, and controlled trial aimed at assessing the efficacy of Lomecel-B in combination with reconstructive surgery compared to surgery alone in 38 infants with HLHS at Stage 2. The trial will be conducted across seven major pediatric centers and consists of two groups: n=19 of placebo vs. n=19 of drug at a dose of 2.5 x 105 cell/kg recipient body weight delivered intramyocardially. The primary endpoint is the change in right ventricular ejection fraction (RVEF) at 12 months post-treatment. This study is being funded by a grant from the National Institutes of Health and has rare pediatric disease, orphan drug, and fast track designations. The first patient was treated in July 2021, and enrollment continues to progress across 7 sites, with one more site planned.

Long-term follow-up data from ELPIS I. As announced on 5/9/23, long-term survival data from the ELPIS I trial showed that all 10 patients who received Lomecel-B during their Stage 2 surgery (Glenn procedure) survived and remained heart transplant-free for up to 5 years of age. All patients have been monitored for at least 3.5 years after treatment; additional long-term follow-up is ongoing. Historical results indicate that children with HLHS have a 20% mortality rate by 5 years. Out of the eligible patients, 5 of 5 have already undergone the third palliative surgery, the last of the standard sequence of surgeries for HLHS, about three years after the Stage 2 surgery. Updated data will be presented at a scientific conference later in 2023.

Lomecel-B in Alzheimer's disease (AD). Lomecel-B works through a multimodal MOA that signals anti-inflammatory, pro-vascular (improved vascular and endothelial function), and regenerative responses. For mild AD, Lomecel-B could be a potential disease-modifying cell therapy by reducing neuroinflammation and improving vascular and endothelial function, targeting multiple disease features. In a prior P1 in mild AD (N=33), Lomecel-B met its primary endpoint of safety, while also demonstrating encouraging results on various exploratory endpoints, including cognition, quality of life, and biomarkers. In addition, patients receiving Lomecel-B also did not develop any amyloid-related imaging abnormalities (ARIA) via MRI. An ongoing P2a CLEAR MIND trial in mild AD (N=48) continues to progress and has completed enrollment as of 11/10/22. Though the primary endpoint is safety within 30 days of first dosing, the study has a 12-month follow-up period and includes a number of efficacy endpoints, including brain volumetry by magnetic resonance imaging (MRI), biomarkers relevant to inflammation and endothelial/vascular systems, and measures of cognitive function. The company expects to report top-line data by YE23.

Japan P2 aging frailty trial underway. The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) approved a Clinical Trial Notification (CTN), equivalent to an IND, allowing Longeveron to sponsor an investigator-initiated P2 clinical study for

aging frailty subjects in Japan. The company subsequently submitted an amendment to the clinical trial design to strengthen the long-term regulatory strategy in Japan, which was accepted on 8/8/22. The amendment changed the primary endpoint to safety, as the Act on the Safety of Regenerative Medicine (ASRM) allows cell therapies to enter the Japanese market with only demonstration of safety in Japanese patients as well as an expectation of efficacy, which could potentially be supported by the prior P2b. An approval under the ASRM could allow Lomecel-B as a treatment for Aging Frailty at select clinical sites. The trial is now underway and is sponsored by the Japanese National Center for Geriatrics and Gerontology. Longeveron has dosed the first patient in the P2 trial (N=45). The study will include three arms: two doses of Lomecel-B and a placebo arm. The primary endpoint of the study is safety, but the study will also evaluate efficacy endpoints to expand the database of the effects of Lomecel-B in elderly patients. Though Japan remains the near-term priority, the company has consulted with the FDA and may advance a parallel program in the US.

Management update. K. Chris Min, M.D., Ph.D., has stepped down from his position as Chief Medical Officer (CMO), effective March 31, 2023, to pursue other opportunities. While an external search is underway to find his replacement, Dr. Min will continue to advise the company in his capacity as Acting Chief Medical Officer to ensure a smooth transition. In addition, James Clavijo, the company's Chief Financial Officer (CFO), has also notified the company of his intent to resign and will remain in his role until June 9, 2023, after which an external search will be conducted to fill the position.

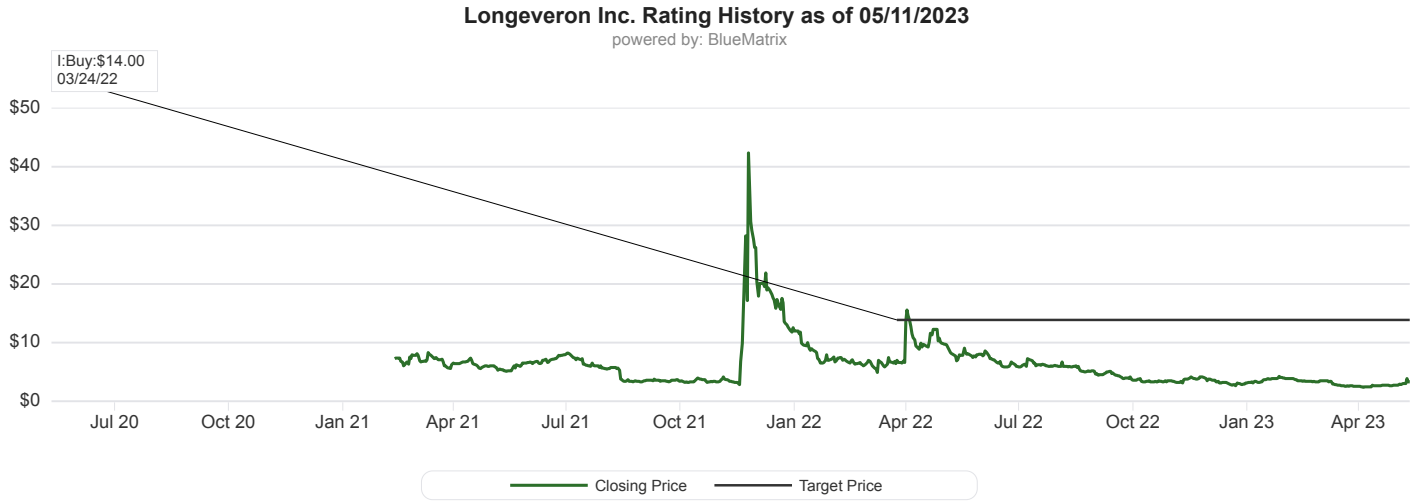
Valuation. We model Lomecel-B in frailty in 2027, hypoplastic left heart syndrome (HLHS) in 2028, and Alzheimer's disease (AD) in 2029, with a 90%, 70%, and 90% revenue risk adjustment, respectively, based on clinical trial risk, regulatory risk, and the difficulty of drug development in a given indication. A 25% discount rate is then applied to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target of $14.

Company description: *Longeveron is a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. The company's lead investigational product is Lomecel-B, an allogeneic medicinal signaling cell (MSC) therapy product isolated from the bone marrow of young, healthy adult donors*

Longeveron, Inc..: Income Statement ($000)																			
YE December 31	1Q22A	2Q22A	3Q22A	4Q22A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Revenue:																			
Lomecel-B in Hypoplastic left heart syndrome	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11,355	28,630	52,638	65,835	77,467
Lomecel-B in Aging frailty	-	-	-	-	-	-	-	-	-	-	-	-	-	79,083	165,948	261,172	365,371	460,032	522,912
Lomecel-B in Alzheimer's disease	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	284,790	478,720	628,679	726,540
Net revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	79,083	177,303	574,592	896,729	1,154,547	1,326,918
Collaborative revenue:																			
Grant, clinical trial, and contract revenue	370	466	265	121	1,222	279				279									
Other Income																			
Total Collaborative Revenue	**370**	**466**	**265**	**121**	**1,222**	**279**	**-**	**-**	**-**	**279**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Total Revenue	**370**	**466**	**265**	**121**	**1,222**	**279**	**-**	**-**	**-**	**279**	**-**	**-**	**-**	**79,083**	**177,303**	**574,592**	**896,729**	**1,154,547**	**1,326,918**
Gross Margins:																			
Cost of Goods Sold - Hypoplastic left heart syndrome												-	-	-	2,271	4,295	6,317	6,584	7,747
%Gross Margin															80%	85%	88%	90%	90%
Cost of Goods Sold - Aging frailty													-	55,358	107,866	156,703	200,954	230,016	261,456
%Gross Margin														30%	35%	40%	45%	50%	50%
Cost of Goods Sold - Alzheimer's disease	-	-	-	-	-	-	-	-	-	-	-				-	85,437	119,680	125,736	145,308
%Gross Margin																70%	75%	80%	80%
Cost of Goods Sold - other	70	306	173	176	725	203				203									
%Gross Margin																			
Gross Profit	300	160	92	(55)	497	76	-	-	-	76	-	-	-	23,725	67,166	328,157	569,779	792,212	912,408
Operating Expenses:																			
Research and Development	1,980	1,720	2,074	3,596	9,370	2,780	2,919	3,065	3,218	10,307	15,050	22,575	31,605	37,926	41,719	43,805	45,995	48,294	50,709
%R&D																			
Selling, General and Administrative	1,714	2,661	3,205	1,590	9,170	2,012	2,113	2,218	2,329	10,087	12,104	14,525	17,430	20,916	25,100	26,355	27,672	29,056	30,509
%SG&A																			
Total Expenses	3,764	4,687	5,452	5,362	19,265	4,995	5,032	5,283	5,547	20,597	27,154	37,100	49,035	114,201	176,955	316,594	400,618	439,686	495,729
Operating Income (loss)	(3,394)	(4,221)	(5,187)	(5,241)	(18,043)	(4,716)	(5,032)	(5,283)	(5,547)	(20,318)	(27,154)	(37,100)	(49,035)	(35,118)	347	257,998	496,112	714,861	831,190
					-					-	-	-	-	-	-	-	-	-	-
Interest and other income	(116)			422	306	69				69	-	-	-	-	-	-	-	-	-
Interest expense										-	-	-	-	-	-	-	-	-	-
Forgiveness of PPP loan					-					-	-	-	-	-	-	-	-	-	-
Non operation lawsuit expense		(1,398)		-	(1,398)					-	-	-	-	-	-	-	-	-	-
Other		(5)	(57)	362	300					-	-	-	-	-	-	-	-	-	-
Total Other Income	**(116)**	**(1,403)**	**(57)**	**784**	**(792)**	**69**	**-**	**-**	**-**	**69**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Pretax Income	(3,510)	(5,624)	(5,244)	(4,457)	(18,835)	(4,647)	(5,032)	(5,283)	(5,547)	(20,249)	(27,154)	(37,100)	(49,035)	(35,118)	347	257,998	496,112	714,861	831,190
Taxes on income	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	24,806	71,486	124,678
Tax Rate																	5%	10%	15%
GAAP Net Income (Loss)	(3,510)	(5,624)	(5,244)	(4,457)	(18,835)	(4,647)	(5,032)	(5,283)	(5,547)	(20,249)	(27,154)	(37,100)	(49,035)	(35,118)	347	257,998	471,306	643,375	706,511
Total comprehensive loss	(3,510)	(5,624)	(5,244)	(4,457)	(18,835)	(4,647)	(5,032)	(5,283)	(5,547)	(20,249)	(27,154)	(37,100)	(49,035)	(35,118)	347	257,998	471,306	643,375	706,511
GAAP-EPS	(0.17)	(0.27)	(0.25)	(0.21)	(0.90)	(0.22)	(0.24)	(0.23)	(0.25)	(0.93)	(0.98)	(1.30)	(1.60)	(1.02)	0.01	7.41	13.49	18.34	20.06
GAAP-EPS (Dil)	(0.17)	(0.27)	(0.25)	(0.21)	(0.90)	(0.22)	(0.24)	(0.23)	(0.25)	(0.93)	(0.98)	(1.30)	(1.60)	(1.02)	0.01	7.41	13.49	18.34	20.06
Wgtd Avg Shrs (Bas) - '000s	20,911	20,944	21,002	21,019	20,969	21,034	21,055	22,576	22,598	21,816	27,662	28,524	30,640	34,520	34,658	34,797	34,936	35,076	35,217
Wgtd Avg Shrs (Dil) - '000s	20,911	20,944	21,002	21,019	20,969	21,034	21,055	22,576	22,598	21,816	27,662	28,524	30,640	34,520	34,658	34,797	34,936	35,076	35,217

Source: Company reports and Maxim

DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 05/11/23
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**86%**	**46%**
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	**14%**	**50%**
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	**0%**	**0%**
	**See valuation section for company specific relevant indices*		

I, **Michael Okunewitch**, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

I, **Jason McCarthy, Ph.D.**, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in Longeveron Inc.

Maxim Group expects to receive or intends to seek compensation for investment banking services from Longeveron Inc. in the next 3 months.

LGVN: For Longeveron Inc., we use the BTK (ARCA Biotechnology Index) as the relevant index.

Valuation Methods
LGVN: We model Lomecel-B in frailty, hypoplastic left heart syndrome (HLHS), and Alzheimer's disease (AD) with revenue risk adjustments, based on clinical trial risk, regulatory risk, and the difficulty of drug development in a given indication. A discount rate is then applied to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target.

Price Target and Investment Risks
LGVN: Aside from general market and other economic risks, risks particular to our price target and rating for Longeveron Inc. include: (1) the regulatory and clinical risk associated with product development; (2) the rate and degree of progress of product development; (3) the rate of regulatory approval and timelines to potential commercialization of products; (4) the level of success achieved in clinical trials; (5) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (6) the liquidity and market volatility of the company's equity securities; (7) regulatory and manufacturing requirements and uncertainties; (8) product and technology developments by competitors, potentially with more resources and commercial infrastructure; (9) inability, of product(s), if approved, to gain adequate market share; (10) impact of comprehensive tax reform in the US and Ex-US tax policy; (11) inability to satisfy existing and/or future debt obligations; (12) the inability of the company to find partners or secure funding for late stage trials; (13) Cell therapy represents fairly high risk development area where we have seen considerable difficulty in trial design and achieving primary outcomes in late stage studies; (14) The company has previously conducted a Phase 2b in aging frailty, but did not achieve the primary endpoint; (15) Aging frailty represents a high risk development area with no approved drugs and little consensus on definition or trial design to support approval, meaning the regulatory pathway will have to be defined in collaboration with regulatory bodies; (16) Alzheimer's disease has historically been an especially challenging area for drug development; (17) the ability to access capital.

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

MAXIM GROUP

Corporate Headquarters

New York City
300 Park Ave., 16TH Floor
New York, NY 10022
Tel: 212-895-3500

Capital Markets/Syndicate
212-895-3695

Corporate Services
212-895-3818

Equity/Options Trading
212-895-3796

Equity Research
212-895-3736

Fixed Income Trading
212-895-3875

South Florida Hub
555 Washington Ave., Suite 320
Miami Beach, FL 33139
Tel: 786-864-0880

Global Equity Trading
212-895-3623

Institutional Sales/Sales Trading
212-895-3873

Prime Brokerage
212-895-3668

Wealth Management
212-895-3540

Stamford, Connecticut
700 Canal Street
Stamford, CT 06902

Red Bank, New Jersey
246 Maple Avenue
Red Bank, NJ 07701
Tel: 732-784-1900

Fort Lauderdale, Florida
1 East Broward Blvd, Suite 1430
Fort Lauderdale, FL 33301

Woodbury, New York
100 Crossways Park Dr West, Suite 207
Woodbury, NY 11797
Tel: 516-393-8300