

Longeveron Announces 2026 Second Quarter Financial Results and Provides Business Update

2026-08-12

- On track for September 2026 top-line results from Phase 2b clinical trial (ELPIS II) evaluating laromestrocel as a potential adjunct treatment for hypoplastic left heart syndrome (HLHS), a rare pediatric disease and orphan-designated indication
- Longeveron selected as a Finalist and Milestone 2 Awardee for the XPRIZE Healthspan competition based on published clinical trial results which indicated laromestrocel increased 6-minute walk distance in patients with aging frailty
- Three new independent Directors join Longeveron's Board of Directors
- Company to host conference call and webcast today at 4:30 p.m. ET

MIAMI, Aug. 12, 2026 (GLOBE NEWSWIRE) -- **Longeveron Inc.** (NASDAQ: LGVN), a clinical stage biotechnology company developing cellular therapy for life-threatening, rare pediatric and chronic aging-related conditions, today reported financial results for the quarter ended June 30, 2026 and provided a business update.

"Longeveron is approaching a series of potentially transformative milestones across our four stem cell therapy development programs that have the potential to redefine the trajectory of our business," said **Stephen H. Willard**, Chief Executive Officer of Longeveron. "Our approach to stem cell therapy development has garnered external recognition and validation with positive clinical data having been published in Nature Medicine and Cell Stem Cell and also serving as the foundation for our selection as a Finalist for the XPRIZE Healthspan competition out of over 600 projects submitted worldwide. We are rapidly approaching the September top line data readout of our ELPIS II Phase 2b clinical trial evaluating laromestrocel in HLHS and look forward to sharing those results."

Development Programs

Longeveron's investigational therapeutic candidate **laromestrocel (Lomecel-B®)** is a proprietary, scalable, allogeneic cellular therapy being evaluated in multiple indications.

Hypoplastic Left Heart Syndrome (HLHS) – 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.

- Topline results from the Phase 2b clinical trial (ELPIS II) evaluating laromestrocel as a potential adjunct therapy for HLHS are anticipated in September 2026.
- In May, the Company **announced** that the U.S. Food and Drug Administration (FDA) held a Type C meeting in late March 2026 focused on the ELPIS II Phase 2b clinical trial and upcoming data readout.
- Also in May, the Company **announced** that the independent Data Monitoring Committee (DMC) completed its final prespecified data review for ELPIS II Phase 2b clinical trial (ELPIS II). The DMC performed a risk-benefit assessment, indicated no safety concerns, and approved the study to continue as designed to completion.
- ELPIS II is being conducted in collaboration with the **National Heart, Lung, and Blood Institute (NHLBI)** through grants from the **National Institutes of Health (NIH)**.
- The FDA has granted laromestrocel Orphan Drug designation, Fast Track designation, and Rare Pediatric Disease designation for the treatment of HLHS.

Pediatric Dilated Cardiomyopathy (PDCM) – a rare pediatric cardiovascular disease in which the muscles in one or more of the heart chambers become enlarged or stretched (dilated), with nearly 40% of children with PDCM requiring a heart transplant or dying within two years of diagnosis.

- Longeveron's Investigational New Drug (IND) application for its stem cell therapy laromestrocel as a potential treatment for PDCM became effective in July 2025. This IND provides for moving directly to a single Phase 2 registrational clinical trial.
- The Company currently anticipates initiation of the Phase 2 clinical trial in 2027, with planning and preparation beginning in 2026.

Alzheimer's disease (AD) – a neurodegenerative disorder that leads to progressive memory loss and death and currently has very limited therapeutic options.

- In July, additional analysis of data from the Phase 2a clinical trial evaluating laromestrocel in mild AD was presented in a Poster Presentation at the **2026 Alzheimer's Association International Conference® (AAIC®)**. The data indicated that laromestrocel reduced neuroinflammation in patients with mild Alzheimer's disease.

- Results from the Phase 2a clinical trial (CLEAR MIND), which support the therapeutic potential of laromestrocel in the treatment of mild Alzheimer's disease and provided evidence-based support for further clinical development, were **published** in the peer-reviewed journal **Nature Medicine** in March 2025.
- Positive Type B meeting with FDA regarding pathway to potential BLA submission for laromestrocel in Alzheimer's disease held in March 2025 with tentative alignment reached on proposed trial study design, population and endpoints for a single Phase 2/3 clinical trial that, if positive, could be acceptable for BLA submission for Alzheimer's disease.
- The FDA has granted laromestrocel both Regenerative Medicine Advanced Therapy (RMAT) designation and Fast Track designation for the treatment of mild Alzheimer's disease.
- The Company is seeking to forge strategic collaborations and/or partnerships for the advancement of laromestrocel in addressing AD.

Aging-related Frailty (AF) – a chronic condition driven by systemic physiologic decline, characterized by reduced reserve and resilience across multiple organ systems with common features including weakness, fatigue, weight loss, slowness and reduced activity. No FDA-approved therapies currently exist.

- Laromestrocel data from its Phase 2b clinical trial in Aging-related Frailty were **published** in **Cell Stem Cell** in February 2026.
- The Phase 2b results indicated that intravenous laromestrocel improved the physical condition of patients with age-related clinical frailty after nine months, compared to placebo.

Corporate Updates

- In April, the Company **announced** that the China National Intellectual Property Administration granted a patent covering potency assay methods for assessing human mesenchymal stem cells (MSCs) derived from bone marrow, adipose tissue, peripheral blood, a lung, a heart, amniotic fluid, inner organs, an amniotic membrane, an umbilical cord or a placenta or differentiated from induced pluripotent stem cells (iPSCs).
- In May, the Company **issued** a CEO Letter to Shareholders highlighting corporate strategy, strategic partnering approach and 2026 key priorities.
- In June, the Company participated in the **BIO International Convention**. Members of the senior management team hosted meetings to explore potential partnership and strategic opportunities for the Company's four stem cell development programs.
- In June, the Company **announced** that it has been granted Small or Medium-sized Enterprise (SME) status by the European Medicines Agency (EMA). The SME program is an initiative by the EMA to address the particular needs of small and medium size companies developing medicinal products in Europe. Companies that are

granted SME designation are able to seek scientific advice, protocol assistance, and other information and training from dedicated EMA personnel during the clinical development process. Companies with this designation can engage in early dialogue with the EMA multidisciplinary team and discuss regulatory strategy with the goal of mitigating delay and accelerating patient access to lifesaving treatments.

- On August 11, 2026, the Company **announced** that it has been selected as a Finalist Team in the **XPRIZE Healthspan** global competition, a seven-year, \$101 million global competition to identify therapeutic approaches to increase human healthspan. As a result, the Company will receive a \$1.0 million Milestone 2 Award to be used towards the future clinical trial required in accordance with the XPRIZE competition rules, with the opportunity to compete for the XPRIZE Grand Prize of up to \$81 million, subject to the successful completion of the required clinical trial and financing thereof.

2026 Second Quarter Summary Financial Results

- Revenues, Cost of Revenues and Gross Profit: Revenues for each of the three-month periods ended June 30, 2026 and June 30, 2025 was \$0.3 million. 2026 revenues decreased by \$29,000, or 10%, when compared to 2025, primarily due to the absence of contract manufacturing revenue.

Clinical trial revenue, which is derived from The Bahamas Registry Trial, for each of the three-month periods ended June 30, 2026 and June 30, 2025 was \$0.3 million. Contract manufacturing revenues for the three months ended June 30, 2026 and 2025, were \$0 and \$18,000, respectively. This decrease of \$18,000, or 100%, when compared to the same period in 2025, was driven by the absence of any additional contract manufacturing services from our third-party client.

Related cost of revenues were \$0.1 million and \$0.2 million for the three months ended June 30, 2026 and 2025, respectively. This resulted in a gross profit of approximately \$0.2 million for the three months ended June 30, 2026, an increase of \$36,000, or 25%, when compared to 2025.

- General and Administrative Expenses: General and administrative expenses for the three months ended June 30, 2026 were \$3.2 million, compared to \$2.6 million for the same period in 2025. The increase of \$0.6 million, or 23%, was primarily due to a \$0.4 million increase in legal spend and a \$0.2 million increase in personnel-related costs.
- Research and Development Expenses: Research and development expenses were \$3.2 million for the three months ended June 30, 2026, compared to \$3.0 million for the same period in 2025. The increase of \$0.2 million, or 7%, was due to higher clinical trial expenses to support the ELPIS II top-line results expected in September 2026.
- Other Income: Other income for the three months ended June 30, 2026 was \$0.1 million, primarily consisting

of interest earned on money market funds. Other income for the three months ended June 30, 2025, was \$0.4 million, primarily consisting of \$250,000 received as a recipient of a Milestone 1 Award in the XPRIZE Healthspan competition and \$0.1 million of interest earned on money market funds.

- Net Loss: Net loss was \$6.1 million for the three months ended June 30, 2026, compared to \$5.0 million for the three months ended June 30, 2025. The increase of \$1.1 million, or 22%, was due to the factors outlined above.
- Cash and cash equivalents: As of June 30, 2026, the Company had cash and cash equivalents of \$10.1 million. We currently anticipate our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2026, based on our current operating budget and cash flow forecast. Our operating costs will continue to be substantial for the foreseeable future in connection with our ongoing activities. We intend to seek additional financing opportunities, capital raises, as well as non-dilutive funding options to support our operating plans.

Conference Call and Webcast Details:

Conference Call Number: 1.877.407.0789
Conference ID: 13761959

Call me™ Feature: [Click Here](#)
Webcast: [Click Here](#)

An archived replay of the webcast will be available on the “**Events & Presentations**” section of the Company’s website following the conference.

About Longeveron Inc.

Longeveron is a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. The Company’s lead investigational product is laromestrocel (Lomecel-B®), an allogeneic mesenchymal stem cell (MSC) therapy product isolated from the bone marrow of young, healthy adult donors. Laromestrocel has multiple potential mechanisms of action encompassing pro-vascular, pro-regenerative, anti-inflammatory, and tissue repair and healing effects with broad potential applications across a spectrum of disease areas. Longeveron is pursuing four pipeline indications: hypoplastic left heart syndrome (HLHS), Alzheimer’s disease, Pediatric Dilated Cardiomyopathy (DCM) and Aging-related Frailty. Laromestrocel development programs have received five distinct and important U.S. FDA designations: for the HLHS program - Orphan Drug designation, Fast Track designation, and Rare Pediatric Disease designation; and, for the AD program - Regenerative Medicine Advanced Therapy (RMAT)

designation and Fast Track designation. For more information, visit www.longeveron.com or follow Longeveron on LinkedIn, X, and Instagram.

Forward-Looking Statements

Certain statements in this press release that are not historical facts are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, which reflect management's current expectations, assumptions, and estimates of future operations, performance and economic conditions, and involve known and unknown risks, uncertainties, and other important factors that could cause actual results, performance, or achievements to differ materially from those anticipated, expressed, or implied by the statements made herein. Forward-looking statements are generally identifiable by the use of forward-looking terminology such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expects," "intend," "looks to," "may," "on condition," "plan," "potential," "predict," "preliminary," "project," "see," "should," "target," "will," "would," or the negative thereof or comparable terminology, although not all forward-looking statements contain these words, or by discussion of strategy or goals or other future events, circumstances, or effects. Factors that could cause actual results to differ materially from those expressed or implied in any forward-looking statements in this release include, but are not limited to, the ability of our clinical trials to demonstrate safety and efficacy of our investigational products, and other positive results; our ability to successfully transition toward a more capital-efficient, asset-light operating model; our ability to secure one or more strategic licensing partnerships for our stem cell therapy laromestrocel in our development programs; our ability to reach alignment with the FDA and other regulatory authorities on a potential path toward regulatory approval of our investigational products; receipt of trial results and other available evidence sufficient to support the Company filing a BLA following the readout of top-line results of the ELPIS II data; the timing and focus of our ongoing and future preclinical studies and clinical trials, and the reporting of data from those studies and trials; market and other conditions, our cash position and need to raise additional capital, the difficulties we may face in obtaining access to capital, and the dilutive impact it may have on our investors; our financial performance, and ability to continue as a going concern; the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements; the size of the market opportunity for certain of our investigational products, including our estimates of the number of patients who suffer from the diseases we are targeting; our ability to scale production and commercialize the investigational products for certain indications; the success of competing therapies that are or may become available; the beneficial characteristics, safety, efficacy and therapeutic effects of our investigational products; our ability to obtain and maintain regulatory approval of our investigational products in the U.S. and other jurisdictions; our plans relating to the further development of our investigational products, including additional disease states or indications we may pursue; our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available and our ability to avoid infringing the intellectual property rights of others; the need to hire additional personnel and our ability to attract and retain such personnel; and our estimates regarding expenses, future revenue, capital requirements and needs

for additional financing.

Further information relating to factors that may impact the Company's results and forward-looking statements are disclosed in the Company's filings with the Securities and Exchange Commission, including Longeveron's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 17, 2026, its Quarterly Reports on Form 10-Q, and its Current Reports on Form 8-K. The Company operates in a highly competitive and rapidly changing environment; therefore, new factors may arise, and it is not possible for the Company's management to predict all such factors that may arise nor assess the impact of such factors or the extent to which any individual factor or combination thereof, may cause results to differ materially from those contained in any forward-looking statements. The forward-looking statements contained in this press release are made as of the date of this press release based on information available as of the date of this press release, are inherently uncertain, and the Company disclaims any intention or obligation, other than imposed by law, to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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Longeveron Inc.
Condensed Balance Sheets
(In thousands, except share and per share data)

	June 30, 2026 (Unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,077	\$ 4,661
Prepaid expenses and other current assets	1,181	686
Accounts receivable	65	104
Total current assets	11,323	5,451
Property and equipment, net	1,602	1,836
Intangible assets, net	2,202	2,285
Operating lease asset, net	348	513
Other assets	12	176
Total assets	<u>\$ 15,487</u>	<u>\$ 10,261</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 633	\$ 423
Accrued expenses	2,653	2,969
Current portion of lease liability	581	655
Deferred revenue	40	40
Other current liabilities	400	—
Total current liabilities	4,307	4,087
Long-term liabilities:		
Long-term portion of operating lease liability	—	169
Liability related to the sale of future PRV proceeds	778	—

Other liabilities	—	330
Total long-term liabilities	<u>778</u>	<u>499</u>
Total liabilities	5,085	4,586
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share, 4,973,025 shares authorized, no shares issued and outstanding at June 30, 2026, and December 31, 2025	—	—
Series A non-voting convertible preferred stock, \$0.001 par value per share, 26,975 shares authorized, 11,542.28 issued and outstanding at June 30, 2026, no shares issued and outstanding at December 31, 2025	—	—
Class A common stock, \$0.001 par value per share, 175,000,000 shares authorized, 30,269,636 shares issued and outstanding at June 30, 2026; 21,445,336 issued and outstanding at December 31, 2025	30	21
Class B common stock, \$0.001 par value per share, 15,705,000 shares authorized, 1,449,005 shares issued and outstanding at June 30, 2026; 1,484,005 shares issued and outstanding at December 31, 2025	1	1
Additional paid-in capital	153,491	137,964
Accumulated deficit	<u>(143,120)</u>	<u>(132,311)</u>
Total stockholders' equity	<u>10,402</u>	<u>5,675</u>
Total liabilities and stockholders' equity	<u>\$ 15,487</u>	<u>\$ 10,261</u>

See accompanying notes to financial statements.

Longeveron Inc.
Condensed Statements of Operations
(In thousands, except per share data)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Revenues				
Clinical trial revenue	\$ 287	\$ 298	\$ 665	\$ 557
Contract manufacturing lease revenue	—	6	—	12
Contract manufacturing revenue	—	12	20	128
Total revenues	<u>287</u>	<u>316</u>	<u>685</u>	<u>697</u>
Cost of revenues	<u>105</u>	<u>170</u>	<u>239</u>	<u>276</u>
Gross profit	182	146	446	421
Operating expenses				
General and administrative	3,159	2,589	5,879	5,530
Research and development	<u>3,194</u>	<u>2,954</u>	<u>5,513</u>	<u>5,469</u>
Total operating expenses	<u>6,353</u>	<u>5,543</u>	<u>11,392</u>	<u>10,999</u>
Loss from operations	(6,171)	(5,397)	(10,946)	(10,578)
Other income				
Other income, net	<u>98</u>	<u>369</u>	<u>137</u>	<u>539</u>
Total other income, net	98	369	137	539
Net loss	<u>\$ (6,073)</u>	<u>\$ (5,028)</u>	<u>\$ (10,809)</u>	<u>\$ (10,039)</u>
Basic and diluted net loss per share	<u>\$ (0.19)</u>	<u>\$ (0.33)</u>	<u>\$ (0.38)</u>	<u>\$ (0.67)</u>
Basic and diluted weighted average common shares outstanding	<u>31,377,630</u>	<u>15,013,072</u>	<u>28,100,164</u>	<u>14,982,075</u>

See accompanying notes to financial statements.

A photo accompanying this announcement is available at

<https://www.globenewswire.com/NewsRoom/AttachmentNg/cde71c09-a5f1-424d-837b-80f8786d82a5>

Source: Longeveron

Stephen Willard

Stephen Willard, Chief Executive Officer, Longeveron Inc. (LGVN)