Larimar Therapeutics Reports Second Quarter 2026 Financial and Business Update

August 4, 2026

- *Positive longer-term open label study data further demonstrated nomlabofusp's well-characterized safety profile, sustained increases in skin frataxin levels, and continued improvements in key clinical outcome measures*
- *High patient and investigator enthusiasm continues with additional participants in the OL study dosed in July and several adults and adolescents in screening as of month-end*
- *Rolling BLA submission seeking accelerated approval underway, with the first module submitted and completion expected 2H 2026*
- *Dosing of first patient in global confirmatory Phase 3 study expected Q3 2026*
- *$156.3 million in cash, cash equivalents and marketable securities as of June 30, 2026, with projected cash runway into the third quarter of 2027*

BALA CYNWYD, Pa., Aug. 04, 2026 (GLOBE NEWSWIRE) -- Larimar Therapeutics, Inc. (Larimar) (Nasdaq: LRMR), a clinical-stage biotechnology company focused on developing treatments for complex rare diseases, today reported its second quarter 2026 operating and financial results.

“This is a defining period for Larimar as we advance nomlabofusp toward potential approval, supported by a clear path to submission, a robust data package, and continued clinical momentum,” said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar. “Open label (OL) study data announced in June further reinforce the disease-modifying potential of nomlabofusp, demonstrating continued directional improvements in key clinical endpoints over time alongside a well-characterized safety profile. Following receipt of minutes from a successful Type B multidisciplinary pre-BLA meeting with the Food and Drug Administration (FDA), the first module of our rolling Biologics License Application (BLA) has been submitted, with completion expected in the second half of 2026. We continue to see strong enthusiasm from patients and investigators as we advance the OL study with additional participants dosed in July and several adults and adolescents in screening. We are also on track to initiate dosing in our global confirmatory study this quarter. Looking ahead, we are focused on execution as we work to bring forward nomlabofusp as the first potential therapy to address the underlying cause of disease for pediatric and adult patients living with Friedreich’s ataxia (FA).”

Highlights

- **June Open Label Study Data Release.** As of June 2026, 43 adolescent and adult participants in the OL study received at least one dose of nomlabofusp and 22 participants remain in the study with a maximum treatment duration of more than 800 days. More than 10,000 doses of nomlabofusp have been administered.
  - **Consistent Long-term Safety Profile**.
    - Longer-term dosing was generally well tolerated with thirteen adults on treatment for one year, seven for 18 months and three for two years.
    - The most common adverse events remained mild-to-moderate local injection site reactions, which decreased in frequency over time and did not lead to any withdrawals from the study.
    - Twenty-one participants discontinued since study initiation in January 2024.
      - Ten participants experienced anaphylaxis and discontinued the study, including nine participants with prior nomlabofusp exposure; all participants who experienced anaphylaxis responded to standard therapy and all returned to their usual state of health with no further sequelae.
      - Three participants experienced generalized urticaria and discontinued the study, with no new occurrences observed following initiation of antihistamine therapy.
      - Other discontinuations included three associated with other adverse events and five discontinuations unrelated to treatment, primarily due to logistical factors.
    - Of the eleven participants who had previously not been exposed to nomlabofusp, one had anaphylaxis.
  - **Sustained Increases in Skin FXN Levels Comparable to Asymptomatic Carriers**. Skin frataxin (FXN) levels increased following nomlabofusp administration, with 82% (9/11) of participants achieving levels above those in asymptomatic carriers by six months, 100% (9/9) reaching this threshold at one year, and 100% (3/3) maintaining it through 18 months.
  - **Improvements in Key Clinical Outcome Measures Relative to FACOMS Natural History Population**.
    - Directional improvement across key clinical endpoints, including mFARS, FARS-ADL, and 9-HPT[1], was sustained following one year of nomlabofusp treatment (n=13) relative to a worsening in those outcomes observed in the Friedreich’s Ataxia Clinical Outcome Measures Study (FACOMS) reference population.

- Nomlabofusp led to a 2.6-point benefit in mFARS at one year.
- Improvement in clinical outcomes was associated with increased skin FXN levels, supporting the potential for nomlabofusp to provide clinical benefit across a broad spectrum of patients with FA, including those with advanced disease.

[1]Modified Friedreich Ataxia Rating Scale (mFARS), FARS-Activities of Daily Living (FARS-ADL), 9-hole peg test (9-HPT)

- **FDA Alignment on BLA Submission Following Multidisciplinary Type B Pre-BLA Meeting:** In June, following minutes from a multidisciplinary Type B pre-BLA meeting and FDA review of the nomlabofusp briefing package, Larimar announced continued agreement with the FDA on key elements of a potential BLA submission including:
  - **Sufficient Data Package:** FDA confirmed that the existing data package appears capable of supporting submission and review of a BLA seeking accelerated approval based on data from the OL study; approval will be a matter of review.
  - **FXN as a Novel Surrogate Endpoint:** FDA reaffirmed its willingness to consider FXN as a novel surrogate endpoint and confirmed that Larimar's exposure-response analysis linking nomlabofusp exposure to clinical outcomes may support the BLA submission.
  - **Gene Expression and Lipid Biomarkers:** FDA stated that the prospectively collected gene expression and lipid biomarker data may provide an opportunity to further characterize the biological activity of nomlabofusp beyond FXN tissue concentrations.
  - **Rolling BLA Submission:** FDA agreed to a rolling BLA submission.
- **Rolling BLA Initiated.** In June, Larimar submitted the first module of its rolling BLA submission seeking accelerated approval.
- **Ongoing Advancement of OL Study**. As of the end of July, additional participants received their initial dose with several adults and adolescents currently in screening.

Upcoming Milestones

- **Global Confirmatory Phase 3 Study:** Dosing of first patient expected Q3 2026.
- **Rolling BLA Submission:** Completion expected 2H 2026 of submission seeking accelerated approval.
- **Launch Timing:** Targeting mid-2027 launch, if approved.

Second Quarter 2026 Financial Results

As of June 30, 2026, the Company had cash, cash equivalents and marketable securities totaling $156.3 million. The Company projects its cash runway into the third quarter of 2027.

Second quarter of 2026 compared to the second quarter of 2025

The Company reported a net loss for the second quarter of 2026 of $32.8 million, or $0.30 per common share, compared to a net loss of $26.2 million, or $0.41 per common share, for the second quarter of 2025.

Research and development expenses for the second quarter of 2026 were $28.0 million compared to $23.4 million for the second quarter of 2025. The increase in research and development expenses was primarily driven by a $2.2 million increase in process performance qualification, and other drug manufacturing activities at our third-party manufacturers and a $2.0 million increase in professional and consulting fees associated with our ongoing and planned clinical trials, data analysis costs, FDA inspection readiness expenditures, as well as BLA preparation costs.

General and administrative expenses were $6.4 million in the second quarter of 2026 compared to $4.4 million in the second quarter of 2025. The increase in general and administrative expenses primarily related to the acceleration of commercial activities as we prepare for the planned mid-2027 launch of nomlabofusp, if approved. This included an increase of $0.7 million of increased compensation costs associated with additional commercial and related headcount, an increase of $0.5 million of market development activities and commercial readiness efforts as well as an increase of $0.5 million in legal fees supporting commercialization and development efforts.

Six months ended June 30, 2026 compared to the six months ended June 30, 2025

The Company reported a net loss for the first six months of 2026 of $62.4 million, or $0.61 per common share, compared to a net loss of $55.5 million, or $0.87 per common share, for the first six months of 2025.

Research and development expenses for the six months ended June 30, 2026, were $53.0 million compared to $49.9 million for the six months ended June 30, 2025. This increase was driven by a $3.7 million increase in professional and consulting fees associated with our ongoing and planned clinical trials, data analysis costs, inspection readiness expenditures as well as BLA preparation costs partially offset by lower manufacturing activities and there related costs in the six month period ended June 30, 2026 compared to the six month period ended June 30, 2026.

General and administrative expenses were $12.4 million for the first six months of 2026 compared to $9.1 million for the six months ended June 30, 2025. The increase in general and administrative expenses primarily related to the acceleration of commercial activities as we prepare for the planned mid-2027 launch of nomlabofusp, if approved. This included an increase of $1.6 million in market research, market development and other commercial readiness activities, an increase of $1.0 million of increased compensation costs associated with additional commercial and related headcount, as well as an increase of $0.5 million in legal fees supporting commercialization and development efforts.

About Larimar Therapeutics
Larimar Therapeutics, Inc. (Nasdaq: LRMR), is a clinical-stage biotechnology company focused on developing treatments for complex rare diseases.

Larimar's lead compound, nomlabofusp, is being developed as a potential treatment for Friedreich's ataxia. Larimar also plans to use its intracellular delivery platform to design other fusion proteins to target additional rare diseases characterized by deficiencies in intracellular bioactive compounds. For more information, please visit: https://larimartx.com.

Forward-Looking Statements

This press release contains forward-looking statements that are based on Larimar's management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including but not limited to statements regarding Larimar's ability to develop and commercialize nomlabofusp and any other planned product candidates, Larimar's planned research and development efforts, including the timing of its nomlabofusp clinical trials, dosing of the first patient in a global confirmatory Phase 3 study, interactions and filings with the FDA, the safety and therapeutic potential of nomlabofusp, expectations regarding the timing of completion of the BLA submission, the expectations of the timing of, and potential for, accelerated approval or accelerated access, time to launch and market and overall development plans and other matters regarding Larimar's business strategies, ability to raise capital, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, among others, the success, cost and timing of Larimar's product development activities, nonclinical studies and clinical trials, including nomlabofusp clinical milestones and continued interactions with the FDA; that preliminary clinical trial results may differ from final clinical trial results, that earlier non-clinical and clinical data and testing of nomlabofusp may not be predictive of the results or success of later non-clinical or clinical trials, and assessments; delays in patient recruitment, including as a result of changes in clinical protocols and adverse events; that the FDA may not ultimately agree with Larimar's nomlabofusp development strategy; Larimar's ability to submit BLA modules on the intended timeline; Larimar's ability to realize the benefits of Breakthrough Therapy Designation; the potential impact of public health crises on Larimar's future clinical trials, manufacturing, regulatory, nonclinical study timelines and operations, and general economic conditions; Larimar's ability and the ability of third-party manufacturers Larimar engages, to optimize and scale nomlabofusp's manufacturing process; Larimar's ability to obtain regulatory approvals for nomlabofusp and future product candidates; Larimar's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators, and to successfully commercialize any approved product candidates; Larimar's ability to raise the necessary capital to conduct its product development activities; and other risks described in the filings made by Larimar with the Securities and Exchange Commission (SEC), including but not limited to Larimar's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the SEC and available at www.sec.gov. These forward-looking statements are based on a combination of facts and factors currently known by Larimar and its projections of the future, about which it cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent Larimar's management's views only as of the date hereof. Larimar undertakes no obligation to update any forward-looking statements for any reason, except as required by law.

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Larimar Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands except share data)
(unaudited)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 92,687	$ 85,412
Marketable securities	63,580	51,440
Prepaid expenses and other current assets	4,405	5,170
Total current assets	160,672	142,022
Property and equipment, net	639	622
Operating lease right-of-use assets	3,055	2,069
Restricted cash	456	606
Other assets	480	523
Total assets	$ 165,302	$ 145,842
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,597	$ 5,216
Accrued expenses	25,367	58,474
Operating lease liabilities, current	1,202	1,105
Total current liabilities	34,166	64,795

Operating lease liabilities	3,754	2,962
Total liabilities	37,920	67,757
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2026 and December 31, 2025; 500,000 and 250,000 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	1	—
Common stock, $0.001 par value per share; 215,000,000 and 115,000,000 shares authorized as of June 30, 2026 and December 31, 2025, respectively; 103,882,937 and 83,090,392 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	103	83
Additional paid-in capital	624,516	512,779
Accumulated deficit	(497,226)	(434,831)
Accumulated other comprehensive gain (loss)	(12)	54
Total stockholders' equity	127,382	78,085
Total liabilities and stockholders' equity	$ 165,302	$ 145,842

Larimar Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 28,000	$ 23,368	$ 53,031	$ 49,919
General and administrative	6,351	4,424	12,437	9,060
Total operating expenses	34,351	27,792	65,468	58,979
Loss from operations	(34,351)	(27,792)	(65,468)	(58,979)
Other income, net	1,569	1,610	3,073	3,516
Net loss	$ (32,782)	$ (26,182)	$ (62,395)	$ (55,463)
Comprehensive loss:				
Net loss	$ (32,782)	$ (26,182)	$ (62,395)	$ (55,463)
Other comprehensive loss:				
Unrealized loss on marketable securities	(18)	(63)	(66)	(157)
Total other comprehensive loss	(18)	(63)	(66)	(157)
Total comprehensive loss	$ (32,800)	$ (26,245)	$ (62,461)	$ (55,620)
Basic and diluted net loss per share:				
Common stock	$ 0.30	$ 0.41	$ 0.61	$ 0.87
Preferred stock	3.01	$ —	6.14	—
Weighted-average shares used in computing basic and diluted net loss per share:				
Common stock	103,882,937	64,027,892	96,887,741	63,996,126
Preferred stock	500,000	—	470,994	—

Source: Larimar Therapeutics