Larimar Therapeutics Reports First Quarter 2026 Financial and Business Update

May 14, 2026

- *Intending to initiate rolling BLA seeking accelerated approval with submission of nonclinical and clinical modules in June 2026; submission of the final modules including the CMC module expected in second half of 2026*
- *Cross-species nonclinical findings that support skin frataxin levels as a surrogate endpoint for nomlabofusp program published in peer-reviewed journal*
- *Topline open label study data to support BLA submission expected in Q2 2026*
- *$200.4 million in cash, cash equivalents and marketable securities as of March 31, 2026, with projected cash runway into the second quarter of 2027*

BALA CYNWYD, Pa., May 14, 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 first quarter 2026 operating and financial results.

"We have strong momentum as we advance nomlabofusp towards potential approval for the treatment of adults and children with Friedreich's ataxia (FA). Our ongoing engagement with the U.S. Food and Drug Administration (FDA) continues to support our registrational strategy. As we are coming down the homestretch for the submission of our BLA, pending FDA feedback, we are planning to seek accelerated approval and initiate a rolling BLA submission in June with the nonclinical and clinical modules. To facilitate a seamless review process, we continue to focus on the completeness of our chemistry, manufacturing, and controls (CMC) module, and plan to submit the CMC portion of the BLA in the second half of 2026," said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar Therapeutics. "We look forward to having a Type B meeting prior to initiating the rolling submission to obtain additional FDA feedback on the BLA content. We expect to report topline data from our open-label (OL) study this quarter and plan to dose the first patient in our global confirmatory Phase 3 study in mid-2026. We are focused on disciplined execution to deliver what could become the first disease-modifying therapy for patients living with FA."

Highlights

- **Published Cross-species Nonclinical Findings on Skin FXN Levels.** In April, Larimar published a paper entitled *Nomlabofusp Treatment Produces Frataxin Levels That Correlate Across Peripheral Tissues: Preclinical and Clinical Support for Surrogate Tissue Sampling* in the peer-reviewed journal *Clinical and Translational Science.* The cross-species nonclinical findings consistently showed that treatment with nomlabofusp increases tissue frataxin (FXN) levels in target tissues (including heart, brain, dorsal root ganglia and skeletal muscle), with changes correlating between the tissues. These data were part of the package reviewed by the U.S. FDA in support of the potential use of skin FXN concentrations as a reasonably likely surrogate endpoint (RLSE) for accelerated approval. The open access article is now available online (https://ascpt.onlinelibrary.wiley.com/doi/10.1111/cts.70565).
- **Breakthrough Therapy Designation:** In February, the U.S. FDA granted Breakthrough Therapy Designation to nomlabofusp for the treatment of adults and children with FA. The designation was based on the FDA's review of available clinical data from the Company's ongoing OL study evaluating nomlabofusp in adult and pediatric patients with FA.
- **FDA Meeting Comments Support Continued Alignment for BLA Submission:** In February, following a recent Support for Clinical Trials Advancing Rare Disease Therapeutics (START) pilot program meeting with the FDA and review of preliminary clinical data for the nomlabofusp program, Larimar announced continued alignment with the FDA on BLA content including:
    - **FXN as Surrogate Endpoint**: FDA reaffirmed willingness to consider use of FXN as novel surrogate endpoint and confirmed Larimar's exposure-response analysis exploring the relationship between nomlabofusp exposures and clinical outcome measures is the type that could support the future BLA submission.
    - **Safety Dataset**: FDA stated that the adequacy of the safety dataset will be a matter of review at the time of BLA submission.

- **Global Phase 3 Study**: FDA is aligned with plans to have the global confirmatory Phase 3 study underway at the time of BLA submission and confirmed that change from baseline in the Upright Stability Score (USS) (a subscale of mFARS) is a reasonable and clinically relevant primary endpoint for the planned Phase 3 study.

- **Strengthened Balance Sheet:** In February, Larimar announced a $115.0 million underwritten public offering of common stock, including the exercise in full of the underwriters' option to purchase additional shares, that included new and existing leading healthcare investors, resulting in net proceeds of $107.6 million and extending its projected cash runway into the second quarter of 2027.

Upcoming Milestones

- **Topline OL Study Data in Second Quarter of 2026:** Larimar plans to report topline data from the OL study that is intended to support BLA submission in the second quarter of 2026.
- **Global Confirmatory Phase 3 Study:** Plan to initiate dosing of first patient mid-2026.

- **BLA Submission:** Type B meeting with FDA scheduled later in Q2 to align on the overall BLA data package readiness. Pending FDA feedback, Larimar is planning to seek accelerated approval in a rolling BLA with submission of nonclinical and clinical modules in June 2026; submission of the final modules including the CMC module expected in second half of 2026. Targeting first half 2027 launch, if approved.

First Quarter 2026 Financial Results

As of March 31, 2026, the Company had cash, cash equivalents and marketable securities totaling $200.4 million.

The Company reported a net loss for the first quarter of 2026 of $29.6 million, or $0.31 per share of common stock, compared to a net loss of $29.3 million, or $0.46 per share of common stock, for the first quarter of 2025.

Research and development expenses for the first quarter of 2026 were $25.0 million, compared to $26.6 million for the first quarter of 2025. The decrease in research and development expenses was primarily driven by a decrease of $3.1 million in nomlabofusp manufacturing related costs and a decrease of $0.5 million in clinical trial costs primarily related to the completion of the Company's adolescent run-in study in the first half of 2025, partially offset by an increase of $1.6 million in professional consulting fees predominantly related to BLA preparation and inspection readiness, and an increase of $0.2 million in personnel expenses due to increased headcount.

General and administrative expenses were $6.1 million in the first quarter of 2026, compared to $4.6 million in the first quarter of 2025. The increase in general and administrative expenses was primarily due to an increase of $1.1 million in professional fees related to commercial consulting services performed and an increase of $0.3 million of personnel costs associated with increased headcount.

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, interactions and filings with the FDA, expectations regarding the timing 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," "target", "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 and Larimar's ability to timely implement the revised dosing regimen in its clinical program for nomlabofusp; 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 clinical trials, and assessments; that the FDA may not ultimately agree with Larimar's nomlabofusp development strategy; that the FDA may not ultimately agree with Larimar's rolling BLA submission strategy; Larimar's ability to submit BLA modules on the intended timelines; 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; the timing of any potential commercial launch of nomlabofusp, if approved; 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 Sheet
(In thousands except share data)
(unaudited)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 177,913	$ 85,412
Marketable securities	22,472	51,440
Prepaid expenses and other current assets	4,592	5,170
Total current assets	204,977	142,022
Property and equipment, net	558	622
Operating lease right-of-use assets	1,866	2,069
Restricted cash	606	606
Other assets	504	523
Total assets	$ 208,511	$ 145,842
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,576	$ 5,216
Accrued expenses	38,123	58,474
Operating lease liabilities, current	1,058	1,105
Total current liabilities	47,757	64,795
Operating lease liabilities	2,721	2,962
Total liabilities	50,478	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 March 31, 2026 and December 31, 2025; 500,000 and 250,000 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	1	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of March 31, 2026 and December 31, 2025; 103,882,937 and 83,090,392 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	103	83
Additional paid-in capital	622,367	512,779
Accumulated deficit	(464,444)	(434,831)
Accumulated other comprehensive gain	6	54
Total stockholders' equity	158,033	78,085
Total liabilities and stockholders' equity	$ 208,511	$ 145,842

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

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 25,031	$ 26,552
General and administrative	6,086	4,636
Total operating expenses	31,117	31,188

Loss from operations	(31,117)	(31,188)
Other income, net	1,504	1,907
Net loss	$ (29,613)	$ (29,281)
Comprehensive loss:		
Net loss	$ (29,613)	$ (29,281)
Other comprehensive loss:		
Unrealized loss on marketable securities	(48)	(94)
Total other comprehensive loss	(48)	(94)
Total comprehensive loss	$ (29,661)	$ (29,375)
Basic and diluted net loss per share:		
Common stock	$ (0.31)	$ (0.46)
Preferred stock	(3.14)	—
Weighted-average shares used in computing basic and diluted net loss per share:		
Common stock	89,814,820	63,964,008
Preferred stock	441,667	—

Source: Larimar Therapeutics