Larimar Therapeutics Reports Third Quarter 2026 Financial and Business Update

November 16, 2026

- *Completed BLA submission seeking accelerated approval of nomlabofusp for adults and pediatric patients with FA; potential to be the first disease-modifying therapy to address root cause of disease*
- *Previously disclosed FDA alignment on key BLA elements, including willingness to consider skin frataxin as a potential novel surrogate endpoint*
- *Patients currently enrolling in FORWARD-FA, the global confirmatory Phase 3 study for nomlabofusp*
- *$128.7 million in cash, cash equivalents and marketable securities as of September 30, 2026, with projected cash runway into late Q2 2027*

BALA CYNWYD, Pa., Nov. 16, 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 third quarter 2026 operating and financial results.

“Completing the BLA submission for nomlabofusp marks a major milestone for Larimar and the Friedreich’s ataxia (FA) community,” said Carole Ben-Maimon, M.D., Chief Executive Officer of Larimar. “The next 12 months are expected to bring several pivotal registrational catalysts, including FDA review of our application and progression of FORWARD-FA, our global confirmatory Phase 3 study. In parallel, we are preparing for a potential U.S. launch in the third quarter of 2027, if approved, while evaluating options to support global commercialization. We are energized by progress across our regulatory, clinical and commercial plans and focused on bringing nomlabofusp to adults and pediatric patients with FA as a therapy designed to address the underlying cause of the disease and potentially alter its course.”

Highlights

- **Submitted BLA**. Larimar completed its rolling BLA submission seeking accelerated approval of nomlabofusp for the treatment of FA using FXN as a novel surrogate endpoint. Approval will be a matter of FDA review. The submission highlights include:
  - Data Package Supporting Submission and Review: FDA reviewed OL study data submitted in a briefing package and confirmed in minutes from the multidisciplinary Type B pre-BLA meeting that the existing data package appears capable of supporting submission and review of a BLA seeking accelerated approval of nomlabofusp as a treatment for patients with FA.
  - FXN as a Potential Surrogate Endpoint: In previously disclosed interactions, FDA reaffirmed its willingness to consider FXN as a novel surrogate endpoint and indicated that Larimar’s exposure-response analysis linking nomlabofusp exposure to clinical outcomes is the type of analysis that could support the BLA submission.
  - Additional Biological Evidence: FDA previously noted that prospectively collected exploratory gene expression and lipid pharmacodynamic markers data may help further characterize the biological activity of nomlabofusp beyond tissue FXN concentrations.
- **Three Poster Presentations at ICAR.** In November, Larimar presented previously disclosed open label study findings and new lipid and gene expression analyses at the 2026 International Congress for Ataxia Research (ICAR).
- **Continued Advancement of OL Study**. Enrollment of additional participants continues in the open label study.

Potential Upcoming Milestones

- **BLA Submission Acceptance:** Early 2027
- **Open Label Study Safety Update:** Q1 2027
- **U.S. Approval:** Mid-2027
- **Obtaining & Monetizing the Rare Pediatric Disease Priority Review Voucher:** Mid-2027, if approved
- **U.S. Launch:** Targeting Q3 2027 launch, if approved.

Third Quarter 2026 Financial Results

As of September 30, 2026, the Company had cash, cash equivalents and marketable securities totaling $128.7 million. The Company projects its cash runway into late Q2 2027.

Third quarter of 2026 compared to the third quarter of 2025

The Company reported a net loss for the third quarter of 2026 of $31.1 million, or $0.29 per common share, compared to a net loss of $47.7 million, or

$0.61 per common share, for the third quarter of 2025.

Research and development expenses for the third quarter of 2026 were $25.9 million compared to $44.9 million for the third quarter of 2025. The decrease in research and development expenses was primarily driven by a $19.3 million decrease in drug manufacturing activities at our third-party manufacturers.

General and administrative expenses were $6.5 million in the third quarter of 2026 compared to $4.6 million in the third quarter of 2025. The increase in general and administrative expenses primarily related to the acceleration of commercial activities as we prepare for the third quarter 2027 launch of nomlabofusp, if approved. This included an increase of $0.6 million in professional fees related to commercial consulting services performed, an increase of $0.5 million in legal fees supporting commercialization and development efforts, an increase of $0.3 million of increased compensation costs associated with additional commercial and related headcount and an increase of $0.3 million of stock compensation costs related to grants issued in 2026.

Nine months ended September 30, 2026 compared to the nine months ended September 30, 2025

The Company reported a net loss for the first nine months of 2026 of $93.5 million, or $0.90 per common share, compared to a net loss of $103.2 million, or $1.50 per common share, for the first nine months of 2025.

Research and development expenses for the nine months ended September 30, 2026, were $79.0 million compared to $94.9 million for the nine months ended September 30, 2025. The decrease in research and development expenses was primarily driven by a $20.1 million decrease in drug manufacturing activities at our third-party manufacturers, partially offset by an increase of $4.1 million in professional, software and consulting fees associated with our ongoing and planned clinical trials, data analysis costs, FDA inspection readiness expenditures, as well as Biologics License Application preparation costs.

General and administrative expenses were $19.0 million for the first nine months of 2026 compared to $13.6 million for the nine months ended September 30, 2025. The increase in general and administrative expenses primarily related to the acceleration of commercial activities as we prepare for planned third quarter 2027 launch of nomlabofusp, if approved. This included an increase of $2.2 million in professional fees related to commercial consulting services performed, an increase of $1.3 million of increased compensation costs associated with additional commercial and related headcount, an increase of $1.0 million in legal fees supporting commercialization and development efforts and an increase of $0.5 million of stock compensation costs related to grants issued in 2026 primarily associated with increased headcount period over period.

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; the potential of nomlabofusp to address the underlying cause of FA and provide clinical benefit; the interpretation of clinical, biomarker and safety data and their ability to support the BLA; expectations regarding the FDA's acceptance for filing, review and potential approval of the BLA, including consideration of skin FXN as a potential novel surrogate endpoint; Larimar's planned research and development efforts, including the design, timing and conduct of FORWARD-FA; interactions with FDA; expectations regarding the potential for, accelerated approval or accelerated access and the impact of such accelerated access on the FDA's review timeline Larimar's preparations for and timing of a potential launch, if approved; the potential award and future sale of a Rare Pediatric Disease Priority Review Voucher; and Larimar's overall development plans, 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 or determine that skin FXN is not an acceptable surrogate endpoint for accelerated approval; that completion of the BLA submission does not assure acceptance for filing or accelerated approval and that FDA may require additional information or studies; 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 successfully 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)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 76,986	$ 85,412
Marketable securities	51,672	51,440
Prepaid expenses and other current assets	7,496	5,170
Total current assets	136,154	142,022
Property and equipment, net	597	622
Operating lease right-of-use assets	2,840	2,069
Restricted cash	456	606
Other assets	457	523
Total assets	$ 140,504	$ 145,842
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,108	$ 5,216
Accrued expenses	29,155	58,474
Operating lease liabilities, current	1,382	1,105
Total current liabilities	35,645	64,795
Operating lease liabilities	3,393	2,962
Total liabilities	39,038	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 September 30, 2026 and December 31, 2025; 500,000 and 250,000 shares issued and outstanding as of September 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 September 30, 2026 and December 31, 2025, respectively; 104,634,619 and 83,090,392 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	104	83
Additional paid-in capital	629,741	512,779
Accumulated deficit	(528,361)	(434,831)
Accumulated other comprehensive (loss) gain	(19)	54
Total stockholders' equity	101,466	78,085
Total liabilities and stockholders' equity	$ 140,504	$ 145,842

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 25,925	$ 44,931	$ 78,956	$ 94,851
General and administrative	6,539	4,568	18,976	13,628
Total operating expenses	32,464	49,499	97,932	108,479
Loss from operations	(32,464)	(49,499)	(97,932)	(108,479)
Other income, net	1,329	1,787	4,402	5,304
Net loss	$ (31,135)	$ (47,712)	$ (93,530)	$ (103,175)
Comprehensive loss:				

Net loss	$ (31,135)	$ (47,712)	$ (93,530)	$ (103,175)
Other comprehensive loss:				
Unrealized loss on marketable securities	(7)	75	(73)	(82)
Total other comprehensive loss	(7)	75	(73)	(82)
Total comprehensive loss	$ (31,142)	$ (47,637)	$ (93,603)	$ (103,257)
Basic and diluted net loss per share:				
Common stock	$ (0.29)	$ (0.61)	$ (0.90)	$ (1.50)
Preferred stock	(2.85)	$ —	(8.98)	—
Weighted-average shares used in computing basic and diluted net loss per share:				
Common stock	104,211,155	78,324,767	99,355,705	68,824,826
Preferred stock	500,000	—	480,769	—

Source: Larimar Therapeutics