Larimar Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results

March 19, 2026

- *Breakthrough Therapy Designation granted to nomlabofusp for the treatment of adults and children with FA based on FDA's review of available clinical data from open label study*
- *Continued alignment with FDA to consider the use of skin FXN to support BLA submission seeking accelerated approval following recent START pilot program meeting*
- *Topline open label study data to support BLA submission expected in Q2 2026*
- *Plan to initiate screening in global Phase 3 confirmatory study in Q2 2026, with dosing of first patient expected mid-2026*
- *Planned BLA submission seeking accelerated approval on track for June 2026; U.S. launch targeted for first-half 2027, if approved*
- *Successful closing of $115 million February 2026 public offering, that included new and existing healthcare focused investors, strengthens balance sheet and extends cash runway*
- *$244.5 million in pro forma* cash, cash equivalents and marketable securities as of December 31, 2025, with projected cash runway into the second quarter of 2027*

**Pro forma cash, cash equivalents, and marketable securities of $244.5 million reflects $136.9 million of cash, cash equivalents and marketable securities as of December 31, 2025 combined with the $107.6 million in net proceeds from the recently completed February 2026 public offering.*

BALA CYNWYD, Pa., March 19, 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 fourth quarter and full year 2025 operating and financial results.

"This is an exciting and pivotal time for Larimar as we continue advancing nomlabofusp toward registration. Receiving Breakthrough Therapy Designation from the Food and Drug Administration (FDA) highlights both the significant unmet needs in Friedreich's ataxia (FA) and the potential of nomlabofusp to address the underlying frataxin (FXN) deficiency that causes the disabilities experienced by people with FA," said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar. "Importantly, our ongoing engagement with the FDA reinforces our registrational path, and we remain on track to submit our Biologics License Application (BLA) seeking accelerated approval in June 2026. In the second quarter of this year, we expect to report topline data from our open label (OL) study, as well as initiate screening in our global confirmatory Phase 3 study. With a strengthened balance sheet following our recent financing and an extended cash runway into the second quarter of 2027, we are strongly positioned to execute on our registrational milestones over the next 12 months. Nomlabofusp has the potential to become the first disease-modifying therapy for FA, and we are committed to delivering it as rapidly as possible to the FA community who continues to face significant unmet medical need."

Highlights

- **Breakthrough Therapy Designation:** In February, the 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 Planned Submission of BLA in June 2026:** In February, following a recent Support for Clinical Trials Advancing Rare Disease Therapeutics (START) pilot program meeting with FDA and review of preliminary clinical data for the nomlabofusp program, Larimar announced continued alignment with the FDA on BLA content including:
    - **FXN as Novel Surrogate Endpoint**: FDA reaffirmed willingness to consider use of FXN as novel surrogate endpoint and confirmed that the preliminary exposure-response data presented exploring the relationship between nomlabofusp exposures and clinical outcome measures is the type that can support the future BLA.

- **Reference Population**: FDA confirmed the process proposed for selecting a reference population based on matched subjects from the Friedrich's Ataxia Clinical Outcomes Measure Study (FACOMS) database for the natural history comparisons of clinical endpoints to be used for the BLA submission and offered to provide advance review and comment on the proposed statistical plan.
- **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 completed a public offering of common stock with net proceeds of $107.6 million that included new and existing leading healthcare investors, extending its projected cash runway into the second quarter of 2027.
- **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 screening in the second quarter of 2026, with dosing of first patient expected mid-2026.
- **BLA Submission on Track:** BLA seeking accelerated approval planned to be submitted in June 2026; U.S. launch targeted for first-half 2027, if approved.

Fourth Quarter and Full Year 2025 Financial Results

As of December 31, 2025, the Company had cash, cash equivalents and marketable securities totaling $136.9 million. Together with net proceeds of approximately $107.6 million from the February 2026 public offering, the Company has projected cash runway into the second quarter of 2027.

The Company reported a net loss for the fourth quarter of 2025 of $62.5 million, or $0.73 per share of common stock, compared to a net loss of $28.8 million, or $0.45 per share of common stock, for the fourth quarter of 2024.

Research and development expenses for the fourth quarter of 2025 were $59.4 million compared to $26.7 million for the fourth quarter of 2024. The rise in research and development expenses was primarily driven by an increase of $30.4 million nomlabofusp manufacturing costs, including process performance qualification and commercialization scale up activities, an increase of $1.5 million in costs associated with ongoing clinical studies, an increase of $0.5 million in professional consulting fees for quality, clinical, and regulatory activities, an increase of $0.3 million in personnel expense primarily due to increased headcount related to nomlabofusp development, and an increase of $0.3 million in non-clinical costs related to assay development and other drug development costs.

General and administrative expenses for both the fourth quarter of 2025 and the fourth quarter of 2024 were $4.6 million due to an increase of $0.4 million in professional consulting fees related to ongoing and increasing commercial activities and offset by a decrease of $0.4 million in non-cash stock compensation expense.

Other income (expense), net was $1.5 million of income in the three months ended December 31, 2025 compared to $2.5 million of income in the three months ended December 31, 2024. The decrease was primarily driven by lower interest and accretion income due to lower interest yields and lower average investable cash, cash equivalents, and marketable securities balances.

For the full year 2025, the Company reported a net loss of $165.7 million, or $2.27 per share of common stock, compared to a net loss of $80.6 million, or $1.32 per share of common stock, for the same period in 2024.

Research and development expenses for the full year 2025 were $154.2 million compared to $73.3 million for the same period in 2024. The rise in research and development expenses was primarily driven by an increase of $63.3 million in nomlabofusp manufacturing costs, including process performance qualification and commercialization scale up activities, an increase of $6.3 million in costs associated with ongoing clinical studies, an increase of $5.9 million in professional consulting fees for quality, clinical, and regulatory activities, an increase of $4.3 million in personnel expense primarily due to increased headcount, and an increase of $2.1 million in non-clinical costs related to assay development and drug development.

General and administrative expenses for the full year 2025 were $18.3 million compared to $17.6 million for 2024. This increase was primarily attributable to an increase of $1.2 million in personnel expense driven by increased headcount and an increase of $0.9 million in professional consulting fees primarily related to ongoing and increasing pre-commercial activities, partially offset by a decrease in non-cash stock compensation expense.

Other income (expense), net was $6.8 million of income in the twelve months ended December 31, 2025 compared to $10.3 million of income in the twelve months ended December 31, 2024. The decrease was primarily driven by lower interest and accretion income due to lower interest yields and lower average investable cash, cash equivalents, and marketable securities balances.

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," "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; 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 Sheet
(In thousands except share data)
(unaudited)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 85,412	$ 33,218
Short-term marketable securities	51,440	150,236
Prepaid expenses and other current assets	5,170	11,850
Total current assets	142,022	195,304
Property and equipment, net	622	881
Operating lease right-of-use assets	2,069	2,838
Restricted cash	606	606
Other assets	523	596
Total assets	$ 145,842	$ 200,225
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,216	$ 2,424
Accrued expenses	58,474	20,872
Operating lease liabilities, current	1,105	1,060
Total current liabilities	64,795	24,356
Operating lease liabilities	2,962	4,057
Total liabilities	67,757	28,413
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 250,000* and no shares issued	—	—

and outstanding as of December 31, 2025 and December 31, 2024, respectively		
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 83,090,392* and 63,815,065 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	83	64
Additional paid-in capital	512,779	440,758
Accumulated deficit	(434,831)	(269,158)
Accumulated other comprehensive gain	54	148
Total stockholders' equity	78,085	171,812
Total liabilities and stockholders' equity	$ 145,842	$ 200,225

** At December 31, 2025, there were 83,090,392 common shares outstanding and 250,000 shares of Series A Convertible Preferred shares outstanding. The Series A Convertible Preferred shares are non-voting but can be converted at any time at the option of the holder into 2,500,000 shares of Common. On a pro-forma basis, there are 85,590,392 common shares outstanding on an as-converted basis.*

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

	Three Months Ended December 31,		Year Ended December 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 59,373	$ 26,738	$ 154,224	$ 73,278
General and administrative	4,645	4,555	18,273	17,612
Total operating expenses	64,018	31,293	172,497	90,890
Loss from operations	(64,018)	(31,293)	(172,497)	(90,890)
Other income, net	1,520	2,469	6,824	10,286
Net loss	$ (62,498)	$ (28,824)	$ (165,673)	$ (80,604)
Comprehensive loss:				
Net loss	$ (62,498)	$ (28,824)	$ (165,673)	$ (80,604)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	(12)	(210)	(94)	67
Total other comprehensive gain (loss)	(12)	(210)	(94)	67
Total comprehensive loss	$ (62,510)	$ (29,034)	$ (165,767)	$ (80,537)
Basic and diluted net loss per share				
Common stock	$ (0.73)	$ (0.45)	$ (2.27)	$ (1.32)
Preferred stock	$ (1.19)	$ —	$ (1.19)	$ —
Weighted-average shares used in computing basic and diluted net loss per share				
Common stock	85,182,783	63,810,823	72,947,927	61,256,084
Preferred stock	250,000	-	250,000	-

Source: Larimar Therapeutics