Larimar Therapeutics Reports Second Quarter 2025 Financial Results

August 14, 2025

- *Initial data from the 50 mg dose in the open label study and the adolescent PK run-in study planned for program update in September 2025*
- *Adolescent participants from the PK run-in study and patients with FA who have not participated in prior nomlabofusp clinical studies are currently screening and enrolling in the open label study; planning to enroll children (2 to 11 years of age) directly into the open label study*
- *FDA recommended that the safety database include at least 30 participants with continuous study drug exposure for 6 months, and a subset of at least 10 participants for 1-year; large majority of safety data should be from participants receiving 50 mg nomlabofusp*
- *Published two peer-reviewed articles; the nonclinical data included in the publications were part of the data submitted to FDA to support the mechanism of action of nomlabofusp and the potential use of skin FXN concentrations as a reasonably likely surrogate endpoint*
- *BLA seeking accelerated approval on track to be submitted in the second quarter of 2026*
- *Global Phase 3 study activities ongoing including qualification of identified sites with patient recruitment expected to initiate later this year*
- *$203.6 million in pro forma* cash, cash equivalents and marketable securities as of June 30, 2025, with projected cash runway into the fourth quarter of 2026*

**Pro forma cash, cash equivalents, and marketable securities of $203.6 million reflects $138.5 million of cash, cash equivalents and marketable securities as of June 30, 2025 combined with the $65.1 million in net proceeds from the recently completed July 2025 public offering.*

BALA CYNWYD, Pa., Aug. 14, 2025 (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 2025 operating and financial results.

"We are pleased with our continued strong execution as we further advance our nomlabofusp program towards potential registration. Importantly, we have written communications in hand from the Food and Drug Administration (FDA) for key elements of our Biologics License Application (BLA) submission including safety database recommendations and a potential accelerated approval pathway based on the use of skin frataxin levels as a novel surrogate endpoint. We also recently published two peer-reviewed papers, including nonclinical data contributing to the FDA's openness to using skin frataxin (FXN) concentrations as a reasonably likely surrogate endpoint (RLSE)," said Carole Ben-Maimon, MD, President, and Chief Executive Officer of Larimar. "Enrollment in our open label study is ongoing, and new study participants are now receiving the lyophilized formulation of nomlabofusp. We have several important near-term catalysts ahead including initial data from the 50 mg dose of our open label study and data from the adolescent pharmacokinetic (PK) run-in study expected in September 2025. Global sites have been identified for our Phase 3 trial, and we expect to initiate patient recruitment later this year. With our balance sheet strengthened through our recent capital raise, key clinical data approaching, and a clear regulatory path in place, we are well-positioned to submit our BLA for nomlabofusp in the second quarter of 2026 as the first potential disease modifying therapy for Friedreich's ataxia (FA)."

Highlights

- **Initial 50 mg Open Label Study Data Expected in September 2025:** The ongoing open label study continues to enroll, and active study participants are currently receiving the 50 mg dose of nomlabofusp. Larimar plans to provide an update on open label data on at least 30 to 40 study participants who received at least one dose of nomlabofusp in September 2025.
- **Adolescent PK Run-In Data in September 2025:** Larimar completed dosing of 14 adolescents (12-17 years of age) in a PK run-in study for pediatric patients with FA in March 2025. Adolescents received a weight-based dose expected to match the PK of adults receiving the 50 mg dose or placebo. The safety and PK data from this study are expected during the

nomlabofusp program update in September 2025.

- **Recent Expansion of Open Label Study Participants**: Adolescent participants from the PK run-in study are currently being screened and enrolled in the open label study. Also, patients with FA who have not participated in prior nomlabofusp clinical studies are being screened and enrolled into the open label study. In addition, Larimar plans to enroll children (2 to 11 years of age) directly into the open label study.

- **Announced FDA Safety Database Recommendations:** In June 2025, Larimar announced that the FDA recommended evaluating safety in at least 30 participants with continuous study drug exposure for 6-months, with a subset of at least 10 of those participants on continuous study drug exposure for 1-year. The FDA also recommended that the large majority of safety data should be from participants receiving the 50 mg dose.

- **Published Nonclinical Data on Nomlabofusp in Two Peer-Reviewed Articles:** In July 2025, Larimar announced the publication of nonclinical data evaluating the mechanism of action, pharmacodynamics, and pharmacology of nomlabofusp as a novel FXN protein replacement therapy designed to address the underlying cause of FA in two peer-reviewed articles. These data were included in the briefing package reviewed by the FDA in support of using skin FXN concentrations as a RLSE for Larimar's registrational program seeking accelerated approval for nomlabofusp.

- **BLA Submission on Track:** In the second quarter of 2026, Larimar plans to submit a BLA seeking accelerated approval.

- **Identified Global Phase 3 Sites:** Following feedback from FDA and European Medicines Agency (EMA) on the study protocol, global Phase 3 study sites in the U.S., E.U., U.K., Canada, and Australia were identified and are currently being qualified and initiated. Larimar expects to begin patient recruitment later this year.

- **Initiated Transition to Lyophilized Form of Nomlabofusp:** In May 2025, Larimar began to introduce the lyophilized product formulation intended for commercialization into the open label study.

- **Strengthened Balance Sheet With $65.1 Million Public Offering:** In July 2025, Larimar announced a public offering of common stock with net proceeds of $65.1 million supported by existing and new leading healthcare investors that extends its projected cash runway into the fourth quarter of 2026.

Second Quarter 2025 Financial Results

As of June 30, 2025, the Company had cash, cash equivalents and marketable securities totaling $138.5 million. Together with net proceeds of approximately $65.1 million from the July 2025 public offering, the company has projected cash runway into the fourth quarter of 2026.

Second quarter of 2025 compared to the second quarter of 2024

The Company reported a net loss for the second quarter of 2025 of $26.2 million, or $0.41 per share, compared to a net loss of $21.6 million, or $0.34 per share, for the second quarter of 2024.

Research and development expenses for the second quarter of 2025 were $23.4 million compared to $19.7 million for the second quarter of 2024. The increase in research and development expenses was primarily attributable to an increase of $2.4 million in professional consulting fees related to ongoing clinical trial activity, an increase of $1.3 million in personnel costs associated with increased headcount as BLA activities expand, and an increase of $0.6 million in clinical costs primarily associated with initial activities related to the design and initial activities associated with the Company's planned confirmatory study required as part of the planned BLA filing.

General and administrative expenses were $4.4 million in the second quarter of 2025 compared to $4.9 million in the second quarter of 2024. The decrease in general and administrative expenses was primarily due to a decrease of $0.4 million in noncash stock compensation costs and a decrease of $0.3 million in professional services primarily related to legal services performed.

Six months ended June 30, 2025, compared to the six months ended June 30, 2024

The Company reported a net loss for the first six months of 2025 of $55.5 million, or $0.87 per share, compared to a net loss of $36.3 million, or $0.62 per share, for the first six months of 2024.

Research and development expenses for the six months ended June 30, 2025, were $49.9 million compared to $32.6 million for the six months ended June 30, 2024. The increase in research and development expenses was primarily attributable to an increase of $7.1 million in nomlabofusp clinical trial material manufacturing costs, an increase of $3.5 million in professional consulting fees related to ongoing clinical trials, an increase of $3.4 million in clinical costs primarily associated with initial activities related to the design and initial activities associated with the Company's planned confirmatory study, and an increase of $2.9 million in personnel costs associated with increased headcount.

General and administrative expenses were $9.1 million for the first six months of 2025 compared to $8.7 million for the six months ended June 30, 2024. The increase in general and administrative expenses was primarily due to an increase of $0.8 million in personnel costs associated with an increased headcount and an increase of $0.3 million in professional services primarily related to pre-marketing-related consulting fees, partially offset by a decrease of $0.7 million in stock compensation costs.

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 potential for accelerated approval or accelerated access and time to 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 clinical trials, and assessments; that the FDA may not ultimately agree with Larimar's nomlabofusp development strategy; 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.

Investor Contact:	**Company Contact:**
Joyce Allaire	Michael Celano
LifeSci Advisors	Chief Financial Officer
jallaire@lifesciadvisors.com	mcelano@larimartx.com
(212) 915-2569	(484) 414-2715

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 20,587	$ 33,218
Short-term marketable securities	117,937	150,236
Prepaid expenses and other current assets	7,032	11,850
Total current assets	145,556	195,304
Property and equipment, net	797	881
Operating lease right-of-use assets	2,468	2,838
Restricted cash	606	606
Other assets	561	596
Total assets	$ 149,988	$ 200,225
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,169	$ 2,424
Accrued expenses	21,351	20,872
Operating lease liabilities, current	1,129	1,060
Total current liabilities	26,649	24,356
Operating lease liabilities	3,485	4,057
Total liabilities	30,134	28,413
Commitments and contingencies		
Stockholders' equity:		

Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2025 and December 31, 2024; no shares issued and outstanding as of June 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of June 30, 2025 and December 31, 2024; 64,027,892 and 63,815,065 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	64	64
Additional paid-in capital	444,420	440,758
Accumulated deficit	(324,621)	(269,158)
Accumulated other comprehensive gain (loss)	(9)	148
Total stockholders' equity	119,854	171,812
Total liabilities and stockholders' equity	$ 149,988	$ 200,225

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,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 23,368	$ 19,682	$ 49,919	$ 32,621
General and administrative	4,424	4,917	9,060	8,712
Total operating expenses	27,792	24,599	58,979	41,333
Loss from operations	(27,792)	(24,599)	(58,979)	(41,333)
Other income, net	1,610	2,972	3,516	5,052
Net loss	$ (26,182)	$ (21,627)	$ (55,463)	$ (36,281)
Net loss per share, basic and diluted	$ (0.41)	$ (0.34)	$ (0.87)	$ (0.62)
Weighted average common shares outstanding, basic and diluted	64,027,892	63,801,792	63,996,126	58,677,749
Comprehensive loss:				
Net loss	$ (26,182)	$ (21,627)	$ (55,463)	$ (36,281)
Other comprehensive loss:				
Unrealized loss on marketable securities	(63)	(125)	(157)	(231)
Total other comprehensive loss	(63)	(125)	(157)	(231)
Total comprehensive loss	$ (26,245)	$ (21,752)	$ (55,620)	$ (36,512)

Source: Larimar Therapeutics