# Larimar Therapeutics Reports Third Quarter 2024 Operating and Financial Results

October 30, 2024

- *Nomlabofusp program update expected mid-December to include available safety, pharmacokinetic (PK) and frataxin data, as well as available clinical outcomes observations from patients with Friedreich's ataxia (FA) receiving 25 mg of nomlabofusp daily for 30-180 days in ongoing open label extension (OLE) study*
- *Initiation of PK run-in study in adolescents on track by year-end 2024*
- *Initiation of global confirmatory/registration study planned mid-2025*
- *Biologics License Application (BLA) submission for nomlabofusp targeted for 2H 2025 to support potential accelerated approval*
- *Strong balance sheet of $203.7 million cash, cash equivalents and marketable securities as of September 30, 2024, with projected cash runway into 2026*

BALA CYNWYD, Pa., Oct. 30, 2024 (GLOBE NEWSWIRE) -- October 30, 2024 – Larimar Therapeutics, Inc. (Larimar) (Nasdaq: LRMR), a clinical-stage biotechnology company focused on developing treatments for complex rare diseases, today reported its third quarter 2024 operating and financial results.

"Our nomlabofusp program continues to advance, with the potential to be the first frataxin protein replacement therapy for patients with FA. All sites are activated with ongoing enrollment in our OLE study evaluating the long-term safety, PK and frataxin levels in patients with FA following daily subcutaneous administration. In mid-December, we plan to provide a development program update that will include available safety, PK, and frataxin data from patients receiving 25 mg of nomlabofusp daily for up to 180 days in our OLE study. We expect to also provide an update on enrollment," said Carole Ben-Maimon, MD, President, and Chief Executive Officer of Larimar. "In November, we look forward to presenting at the International Congress for Ataxia Research (ICAR) meeting new data on results from our completed dose exploration study including exploratory gene and lipid expression results following nomlabofusp treatment. In addition, we will also be presenting two posters with data from patients participating in our Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) studies and Phase 2 dose exploration study. One poster will provide patient data on baseline disease characteristics and baseline tissue frataxin levels, and the other will present the relationship between dose, PK and tissue frataxin levels using modeling and simulation. We remain on track to initiate a PK run-in study in adolescent patients with FA in the fourth quarter of this year which is the first step towards evaluating nomlabofusp treatment in pediatric patients."

Dr. Ben-Maimon continued, "On the regulatory front, we were pleased to recently receive Innovative Licensing and Access Pathway (ILAP) designation from the Medicines and Healthcare Products Regulatory Agency (MHRA) which aims to facilitate patient access by accelerating time to market in the U.K. We also held our first meetings with the Food and Drug Administration (FDA) as part of the Support for Clinical Trials Advancing Rare Disease Therapeutics (START) pilot program and appreciate the dialogue and interaction designed to help advance our development program. In parallel, we began work to further understand the continued areas of unmet need in the FA therapeutic landscape from the perspective of physicians, payers, and most importantly, patients. We will use this information to develop our commercial approach and to refine our market entry strategy. Finally, we continue scaling up our manufacturing efforts and collecting required data to support a potential accelerated approval path. Our targeted BLA submission remains on track for the second half of 2025."

**Recent Highlights**

- Today, Larimar announced that it will provide a nomlabofusp development program update in mid-December 2024 that will include available safety, PK and frataxin data, as well as available clinical outcomes observations from patients currently receiving a daily 25 mg dose of nomlabofusp for approximately 30 to 180 days in the OLE study. An update on enrollment in the OLE study will also be provided.
- Larimar recently received ILAP designation from the MHRA for nomlabofusp for the treatment of adults and children with FA. ILAP aims to facilitate patient access to novel treatments by accelerating time to market through opportunities for enhanced engagements with U.K. regulatory authorities and other stakeholders. Along with the receipt of the ILAP designation, nomlabofusp has already been granted orphan drug designations in the U.S. and the European Union (EU), Fast Track and Rare Pediatric Disease designations in the U.S., PRIME designation in the EU, and selected to be in the START pilot program by the FDA.
- Larimar is on track to initiate by year-end a PK run-in study in an initial cohort of 12-15 adolescents (12 to 17 years of age) with FA. Initiation of a second cohort of 12-15 children (2 to 11 years of age) is planned to follow next year. Study

participants will be randomized 2:1 to receive either nomlabofusp or placebo daily. Following assessment of safety and exposure data of each cohort in the PK run-in study, participants will be eligible to screen for the OLE study.

- Larimar is on track for a planned initiation of a global confirmatory/registration study planned mid-2025 with potential sites in the U.S., Europe, U.K., Canada, and Australia. Larimar continues to target BLA submission for the second half of 2025 to support accelerated approval.
- In September 2024, Larimar announced that data from the Company's nomlabofusp Phase 1 studies and Phase 2 dose exploration study, some of which has been previously disclosed, will be presented at the ICAR meeting being held November 12-15, 2024, in London, U.K.

**Third Quarter 2024 Financial Results**
As of September 30, 2024, the Company had cash, cash equivalents and marketable securities totaling $203.7 million, which provides projected cash runway into 2026.

*Third quarter of 2024 compared to the third quarter of 2023*

The Company reported a net loss for the third quarter of 2024 of $15.5 million, or $0.24 per share, compared to a net loss of $9.1 million, or $0.21 per share, for the third quarter of 2023.

Research and development expenses for the third quarter of 2024 were $13.9 million compared to $6.6 million for the third quarter of 2023. The increase in research and development expenses was primarily driven by an increase of $3.8 million in nomlabofusp manufacturing costs including lyophilization development, production scaling costs and manufacturing costs related to producing doses to be used in ongoing and planned clinical trials, an increase of $1.1 million in personnel expense due to increased headcount, an increase of $0.9 million in assay development costs, an increase of $0.6 million in clinical costs primarily associated with the OLE study which began dosing patients in the first quarter of 2024, an increase of $0.3 million of professional fees related to consulting costs, an increase of $0.2 million in stock compensation costs associated with 2024 grants and an increase of $0.2 million in internal lab costs.

General and administrative expenses were $4.3 million in the third quarter of 2024 compared to $3.8 million in the third quarter of 2023. The increase in general and administrative expenses was primarily driven by an increase of $0.4 million in personnel expense and an increase of $0.2 million in professional fees primarily related to consulting costs related to commercial activity and other public company related expenses.

*Nine months ended September 30, 2024 compared to the nine months ended September 30, 2023*

The Company reported a net loss for the 9-month period ending September 30, 2024 of $51.8 million, or $0.86 per share, compared to a net loss of $24.0 million, or $0.55 per share, for the 9-month period ending September 30, 2023.

Research and development expenses for the 9-month period ending September 30, 2024 were $46.5 million compared to $17.0 million for the 9-month period ending September 30, 2023. The increase in research and development expenses was primarily driven by an increase of $20.2 million in nomlabofusp manufacturing costs including lyophilization development, production scaling costs and manufacturing costs related to producing doses to be used in ongoing and planned clinical trials, an increase of $3.2 million in personnel expense due to increased headcount, an increase of $2.9 million in clinical costs primarily associated with the OLE study which began dosing patients in the first quarter of 2024, increase of $0.9 million in assay development costs, an increase of $0.8 million related to the Track-FA program, an increase of $0.5 million in stock compensation costs associated with 2024 grants, an increase of $0.5 million in internal lab costs and an increase of $0.3 million of professional fees related to consulting costs.

General and administrative expenses for the 9-month period ending September 30, 2024 were $13.1 million compared to $10.6 million for the 9-month period ending September 30, 2023. The increase in general and administrative expenses was primarily driven by an increase of $1.0 million in personnel expense, an increase of $1.0 million in professional fees primarily related to consulting costs related to commercial activity and other public company related expenses, an increase of $0.3 million of other expense related to computer software, information technology services and recruiting and an increase of $0.2 million in stock compensation costs associated with 2024 grants.

**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 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 plan 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:**
Joyce Allaire
LifeSci Advisors
jallaire@lifesciadvisors.com
(212) 915-2569

**Company Contact:**
Michael Celano
Chief Financial Officer
mcelano@larimartx.com
(484) 414-2715

**Larimar Therapeutics, Inc.**
Condensed Consolidated Balance Sheet
(unaudited)

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 35,067 | $ 26,749 |
| Short-term marketable securities | 168,640 | 60,041 |
| Prepaid expenses and other current assets | 9,549 | 3,385 |
| Total current assets | 213,256 | 90,175 |
| Property and equipment, net | 779 | 684 |
| Operating lease right-of-use assets | 3,026 | 3,078 |
| Restricted cash | 1,339 | 1,339 |
| Other assets | 621 | 659 |
| Total assets | $ 219,021 | $ 95,935 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,686 | $ 1,283 |
| Accrued expenses | 13,573 | 7,386 |
| Operating lease liabilities, current | 1,026 | 837 |
| Total current liabilities | 16,285 | 9,506 |
| Operating lease liabilities | 4,336 | 4,709 |
| Total liabilities | 20,621 | 14,215 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of September 30, 2024 and December 31, 2023; no shares issued and outstanding as of September 30, 2024 and December 31, 2023 | — | — |
| Common stock, $0.001 par value per share; 115,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 63,806,628 and 43,909,069 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 64 | 43 |
| Additional paid-in capital | 438,312 | 270,150 |
| Accumulated deficit | (240,334) | (188,554) |
| Accumulated other comprehensive gain | 358 | 81 |
| Total stockholders' equity | 198,400 | 81,720 |
| Total liabilities and stockholders' equity | $ 219,021 | $ 95,935 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Operating expenses: | | | | |
| Research and development | $ 13,919 | $ 6,585 | $ 46,540 | $ 17,022 |
| General and administrative | 4,345 | 3,754 | 13,057 | 10,574 |
| Total operating expenses | 18,264 | 10,339 | 59,597 | 27,596 |
| Loss from operations | (18,264) | (10,339) | (59,597) | (27,596) |
| Other income, net | 2,765 | 1,275 | 7,817 | 3,640 |
| Net loss | $ (15,499) | $ (9,064) | $ (51,780) | $ (23,956) |
| Net loss per share, basic and diluted | $ (0.24) | $ (0.21) | $ (0.86) | $ (0.55) |
| Weighted average common shares outstanding, basic and diluted | 63,806,158 | 43,903,738 | 60,399,697 | 43,899,670 |
| Comprehensive loss: | | | | |
| Net loss | $ (15,499) | $ (9,064) | $ (51,780) | $ (23,956) |
| Other comprehensive gain (loss): | | | | |
| Unrealized gain (loss) on marketable securities | 508 | (5) | 277 | 38 |
| Total other comprehensive gain (loss) | 508 | (5) | 277 | 38 |
| Total comprehensive loss | $ (14,991) | $ (9,069) | $ (51,503) | $ (23,918) |

Source: Larimar Therapeutics