Larimar Therapeutics Reports Second Quarter 2024 Operating and Financial Results

August 7, 2024

- *Open label extension (OLE) study is progressing with all 7 sites activated; interim data planned for Q4 2024*
- *Selected by Food and Drug Administration (FDA) to participate in Support for Clinical Trials Advancing Rare Disease Therapeutics (START) pilot program for nomlabofusp*
- *Joined TRACK-FA Neuroimaging Consortium as an industry partner; TRACK-FA collects natural history data to establish disease-specific neuroimaging biomarkers for potential use in clinical trials*
- *Planning initiation of pharmacokinetic (PK) run-in study in adolescents by year-end 2024; plan to transition adolescents into ongoing OLE study upon completion of PK study*
- *Planning initiation of global confirmatory study by mid-2025 with potential sites in the U.S., Europe, U.K., Canada, and Australia*
- *Biologics License Application (BLA) filing targeted for 2H 2025 to support accelerated approval*
- *Strong balance sheet of $226.1 million cash, cash equivalents and marketable securities as of June 30, 2024, with projected cash runway into 2026*

BALA CYNWYD, Pa., Aug. 07, 2024 (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 2024 operating and financial results.

“We made significant achievements in our nomlabofusp program this quarter that strongly position us for successful execution across important catalysts over the next 12 months. We were honored to be selected by the FDA to participate in the START pilot program which may be invaluable in helping us achieve our timeline for BLA submission targeted for the second half of 2025 to support accelerated approval. We are actively pursuing clinical sites in the U.S., Europe, U.K. Canada, and Australia in anticipation of initiating a global confirmatory study in mid-2025. We are excited to have recently joined the TRACK-FA Neuroimaging Consortium as an industry partner to support research to define disease-specific neuroimaging biomarkers for potential use in clinical trials.” said Carole Ben-Maimon, MD, President, and Chief Executive Officer of Larimar. “Our OLE study continues to progress with all seven sites now activated and interim data planned for the fourth quarter of this year. We plan to initiate a PK run-in study in adolescents with Friedreich’s ataxia (FA) by year-end, with option for study participants to transition to the OLE study after completing the run-in study. Expanding our clinical program into younger patients will allow us to evaluate the effect of nomlabofusp earlier in the disease process which may help further address the effect of the underlying frataxin deficiency in patients with FA.”

Recent Highlights

- Today, Larimar announced it is planning a PK run-in study in adolescents (12 to 17 years of age) and children (2 to 11 years of age) with FA. This study which we plan to initiate by year-end, will initially enroll 12-15 adolescent patients who will be randomized 2:1 to receive either nomlabofusp or placebo daily. Study participants can transition to the OLE study after completing the PK run-in study.
- Today, Larimar announced that all 7 sites of the OLE were activated. The OLE study continues to progress with interim data to be reported in the fourth quarter of the year.
- In June 2024, Larimar entered into an agreement with the Friedreich’s Ataxia Research Alliance (FARA) to join the TRACK-FA Neuroimaging Consortium that includes pharmaceutical, biotechnology, academic and clinical partners. The consortium will conduct a natural history study designed to establish disease-specific neuroimaging biomarkers to track disease progression in the brain and spinal cord and provide a basis for utilizing these biomarkers in clinical trials. Using longitudinal data from large cohorts of patients compared to controls, the study will assess changes in areas previously shown to be compromised in individuals with FA. As an industry partner, Larimar will help fund the study and contribute to the study design, research activities, and analysis. Larimar will have access to all study data for use in its regulatory filings, as appropriate.
- In May 2024, Larimar announced that the FDA has selected the nomlabofusp development program as one of a select few programs to participate in the START pilot program. START selection was based on demonstrated development program readiness, including the potential of nomlabofusp to address the serious and unmet medical needs in a rare neurodegenerative condition, alignment of chemistry, manufacturing, and controls (CMC) development timelines with clinical development plans, and a proposed communications plan where enhanced communication could accelerate pivotal study initiation and path to potential BLA submission.

Second Quarter 2024 Financial Results

As of June 30, 2024, the Company had cash, cash equivalents and marketable securities totaling $226.1 million, which provides projected cash runway into 2026.

Second quarter of 2024 compared to the second quarter of 2023

The Company reported a net loss for the second quarter of 2024 of $21.6 million, or $0.34 per share, compared to a net loss of $8.4 million, or $0.19 per share, for the second quarter of 2023.

Research and development expenses for the second quarter of 2024 were $19.7 million, compared to $5.9 million for the second quarter of 2023. This $13.8 million increase is attributable to increased nomlabofusp manufacturing costs of $10.6 million, including costs related to increasing production costs, $2.1 million due to increased clinical trial costs, primarily the OLE and costs associated with the TRACK-FA natural history study and $1.1M of additional costs associated with increasing headcount.

General and administrative expenses were $4.9 million in the second quarter of 2024, compared to $3.7 million in the second quarter of 2023, an increase of $1.2 million. This increase is attributable in part to $0.6 million in increased legal and professional fees, $0.4 million in additional personnel costs driven by increasing headcount and an increase of $0.1 million in increased non-cash stock compensation costs.

Six months ended June 30, 2024 compared to the six months ended June 30, 2023

The Company reported a net loss for the first six months of 2024 of $36.3 million, or $0.62 per share, compared to a net loss of $14.9 million, or $0.34 per share, for the first six months of 2023.

Research and development expenses for the six months ended June 30, 2024 were $32.6 million, compared to $10.4 million for the six months ended June 30, 2023. This $22.2 million increase is attributable to increased nomlabofusp manufacturing costs of $16.3 million, $3.1 million due to increased clinical trial costs, primarily the OLE and costs associated with the TRACK-FA natural history study, $2.0M of additional costs associated with increasing headcount and $0.3 million of increased noncash stock compensation expense.

General and administrative expenses were $8.7 million for the first six months of 2024, compared to $6.8 million for the six months ended June 30, 2023, an increase of $1.9 million. This increase is attributable in part to $0.8 million in increased legal and professional fees, $0.6 million of additional personnel costs driven by increasing headcount and an increase of $0.3 million in increased non-cash 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 other planned product candidates, Larimar's planned research and development efforts, including the timing of its nomlabofusp clinical trials, interactions with the FDA 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 32,311	$ 26,749
Short-term marketable securities	193,753	60,041
Prepaid expenses and other current assets	5,066	3,385
Total current assets	231,130	90,175
Property and equipment, net	844	684
Operating lease right-of-use assets	3,213	3,078
Restricted cash	1,339	1,339
Other assets	636	659
Total assets	$ 237,162	$ 95,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,917	$ 1,283
Accrued expenses	17,246	7,386
Operating lease liabilities, current	992	837
Total current liabilities	21,155	9,506
Operating lease liabilities	4,603	4,709
Total liabilities	25,758	14,215
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2024 and December 31, 2023; no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 63,802,517 and 43,909,069 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	64	43
Additional paid-in capital	436,325	270,150
Accumulated deficit	(224,835)	(188,554)
Accumulated other comprehensive gain (loss)	(150)	81
Total stockholders' equity	211,404	81,720
Total liabilities and stockholders' equity	$ 237,162	$ 95,935

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 19,682	$ 5,875	$ 32,621	$ 10,437
General and administrative	4,917	3,745	8,712	6,820
Total operating expenses	24,599	9,620	41,333	17,257
Loss from operations	(24,599)	(9,620)	(41,333)	(17,257)
Other income (expense), net	2,972	1,254	5,052	2,365
Net loss	(21,627)	(8,366)	(36,281)	(14,892)
Net loss per share, basic and diluted	$ (0.34)	$ (0.19)	$ (0.62)	$ (0.34)
Weighted average common shares outstanding, basic and diluted	63,801,792	43,897,603	58,677,749	43,897,603
Comprehensive loss:				
Net loss	$ (21,627)	$ (8,366)	$ (36,281)	$ (14,892)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	(125)	12	(231)	43

Total other comprehensive gain (loss)	(125)	12	(231)	43
Total comprehensive loss	$ (21,752)	$ (8,354)	$ (36,512)	$ (14,849)

Source: Larimar Therapeutics