Larimar Therapeutics Reports Second Quarter 2023 Operating and Financial Results

August 10, 2023

- *Initiation cleared for 50 mg cohort in Phase 2 Friedreich's ataxia (FA) dose exploration trial following FDA review of unblinded 25 mg cohort Phase 2 data*
- *Initiation cleared for open-label extension (OLE) trial following FDA review of unblinded 25 mg cohort Phase 2 data*
- *Top-line safety, pharmacokinetic, and frataxin data from the Phase 2 trial's 50 mg cohort expected in 1H 2024*
- *Initiation of OLE trial with 25 mg daily dosing expected in Q1 2024; interim data expected in Q4 2024*
- *Cash, cash equivalents and marketable securities of $104.2 million as of June 30, 2023, provides projected cash runway into Q4 2024*

BALA CYNWYD, Pa., Aug. 10, 2023 (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 operating and financial results.

"Advancing our 50 mg cohort in our Phase 2 study and initiating our OLE study following FDA review of unblinded Phase 2 data from our 25 mg cohort are major advances in the development of CTI-1601 as potentially the first therapy designed to increase frataxin levels and address the underlying deficiency driving FA's devastating clinical course," said Carole Ben-Maimon, MD, President, and Chief Executive Officer of Larimar. "We are pleased to see that 25 mg was generally well tolerated and increased frataxin levels when dosed daily for 14 days. We are also very excited to now be able to initiate long-term dosing in the OLE trial in patients who participated in our Phase 1 or Phase 2 studies. The ability to follow patients in a long-term study that will assess increases in frataxin over months is very important to moving the development program forward."

Dr. Ben-Maimon continued, "As we look ahead, we are focused on initiating our 50 mg cohort shortly, and plan to initiate our OLE trial in the first quarter of 2024. We expect to report top-line safety, pharmacokinetic, and frataxin data from the 50 mg cohort of our Phase 2 trial in the first half of 2024, and interim data from the OLE trial in the fourth quarter of 2024. Importantly, these trials will inform our future dose and dose regimen selection, as well as help to explore the long-term safety and pharmacokinetic and pharmacodynamic profiles of CTI-1601. With these key milestones ahead of us, coupled with our robust clinical dataset, we believe we are well-positioned to further advance the development of CTI-1601, with its unique mechanism of action and potential to be disease modifying for patients with FA."

Second Quarter and Subsequent Highlights

- In July 2023, following FDA review of unblinded safety, pharmacokinetic, and frataxin data from the Phase 2 trial's 25 mg cohort, Larimar received FDA clearance to initiate both a 50 mg cohort in the Phase 2 dose exploration trial evaluating CTI-1601 for FA and an OLE trial. Initiation of additional U.S. clinical trials are contingent on FDA review of Phase 2 data from the 50 mg cohort and any available data from the OLE due to the partial clinical hold.

- In May 2023, Larimar announced top-line data from the 25 mg cohort of its ongoing Phase 2, four-week, placebo-controlled, dose exploration trial of CTI-1601 for the treatment of FA. Data from the 25 mg cohort demonstrated that daily subcutaneous injections of 25 mg CTI-1601 for 14 days were generally well-tolerated and led to increases in frataxin levels from baseline compared to placebo in all evaluated tissues (skin and buccal cells).

- In July 2023, Larimar strengthened its executive clinical leadership with the appointment of Russell "Rusty" Clayton, DO, as Chief Medical Officer. As one of Larimar's closest advisors for the last 5 years, Dr. Clayton has attended every meeting between Larimar and the FDA and has been chair of Larimar's Scientific Advisory Board since inception. Dr. Clayton succeeds former CMO Nancy M. Ruiz, MD following her retirement.

- In June 2023, Larimar joined the broad-market Russell 3000 Index with inclusion in the large-cap Russell 1000 Index or small-cap Russell 2000 Index and appropriate growth and value style indexes.

Second Quarter 2023 Financial Results

As of June 30, 2023, the Company had cash, cash equivalents and marketable securities totaling $104.2 million, which provides projected cash runway into the fourth quarter of 2024.

The Company reported a net loss for the second quarter of 2023 of $8.4 million, or $0.19 per share, compared to a net loss of $8.7 million, or $0.47 per share, for the second quarter of 2022.

Research and development expenses for the second quarter of 2023 were $5.9 million compared to $5.6 million for the second quarter of 2022. The

increase in research and development expenses was primarily driven by an increase of $0.5 million in test method development and optimization, an increase of $0.4 million in personnel related costs, an increase of $0.2 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023, partially offset by a decrease of $1.1 million in clinical supply manufacturing costs.

General and administrative expenses for the second quarter of 2023 were $3.7 million compared to $3.0 million for the second quarter of 2022. This increase was primarily driven by an increase of $0.3 million of professional fees primarily related to increased legal expense, an increase of $0.2 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023 and an increase of $0.2 million in personnel related costs.

The Company reported a net loss for the first half of 2023 of $14.9 million, or $0.34 per share, compared to a net loss of $17.6 million, or $0.96 per share, for the first half of 2022.

Research and development expenses for the first half of 2023 were $10.4 million compared to $11.5 million for the first half of 2022. The decrease in research and development expenses was primarily driven by a decrease of $1.5 million in clinical supply manufacturing costs, a decrease in assay development costs of $0.2 million partially offset by an increase of $0.5 million in personnel related costs, an increase of $0.3 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023.

General and administrative expenses for the first half of 2023 were $6.8 million compared to $6.1 million for the first half of 2022. The increase in general and administrative expense was primarily driven by an increase of $0.3 million in stock-based compensation expense associated with stock option grants made in 2022 and 2023, an increase of $0.3 million of professional fees primarily related to legal expense, and an increase of $0.2 million in personnel related 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, CTI-1601, 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 Larimar's ability to develop and commercialize CTI-1601 and other planned product candidates, Larimar's planned research and development efforts, including the timing of its CTI-1601 clinical trials 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 CTI-1601 clinical milestones and continued interactions with the FDA regarding the partial clinical hold; that preliminary clinical trial results may differ from final clinical trial results, that earlier non-clinical and clinical data and testing of CTI-1601 may not be predictive of the results or success of later clinical trials, and assessments; 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 CTI-1601's manufacturing process; Larimar's ability to obtain regulatory approvals for CTI-1601 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.
Condensed Consolidated Balance Sheet
(unaudited)

	June 30, 2023	December 31, 2022
Assets		

Current assets:		
Cash and cash equivalents	$ 94,321	$ 26,825
Marketable securities	9,879	91,603
Prepaid expenses and other current assets	2,278	2,311
Total current assets	106,478	120,739
Property and equipment, net	677	831
Operating lease right-of-use assets	2,578	2,858
Restricted cash	1,339	1,339
Other assets	644	638
Total assets	$ 111,716	$ 126,405
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,344	$ 1,686
Accrued expenses	4,365	8,408
Operating lease liabilities, current	566	611
Total current liabilities	7,275	10,705
Operating lease liabilities	4,511	4,797
Total liabilities	11,786	15,502
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2023 and December 31, 2022; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 43,269,200 shares issued and outstanding as of June 30, 2023 and December 31, 2022	43	43
Additional paid-in capital	266,372	262,496
Accumulated deficit	(166,497)	(151,605)
Accumulated other comprehensive loss	12	(31)
Total stockholders' equity	99,930	110,903
Total liabilities and stockholders' equity	$ 111,716	$ 126,405

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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 5,875	$ 5,644	$ 10,437	$ 11,450
General and administrative	3,745	3,043	6,820	6,124
Total operating expenses	9,620	8,687	17,257	17,574
Loss from operations	(9,620)	(8,687)	(17,257)	(17,574)
Other income (expense), net	1,254	20	2,365	(36)
Net loss	$ (8,366)	$ (8,667)	$ (14,892)	$ (17,610)
Net loss per share, basic and diluted	$ (0.19)	$ (0.47)	$ (0.34)	$ (0.96)
Weighted average common shares outstanding, basic and diluted	43,897,603	18,338,853	43,897,603	18,338,853
Comprehensive loss:				
Net loss	$ (8,366)	$ (8,667)	$ (14,892)	$ (17,610)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	12	(57)	43	(57)
Total other comprehensive gain (loss)	12	(57)	43	(57)
Total comprehensive loss	$ (8,354)	$ (8,724)	$ (14,849)	$ (17,667)



Source: Larimar Therapeutics