Larimar Therapeutics Reports First Quarter 2022 Operating and Financial Results

May 12, 2022

- CTI-1601 Type C Meeting to discuss clinical hold has been granted by the U.S. Food and Drug Administration and is scheduled for early in the third quarter of 2022

- Cash at March 31, 2022 of $62.6 million provides projected cash runway into the third quarter of 2023

BALA CYNWYD, Pa., May 12, 2022 (GLOBE NEWSWIRE) -- Larimar Therapeutics, Inc. ("Larimar") (Nasdaq: LRMR), a clinical-stage biotechnology company focused on developing treatments for complex rare diseases, today reported its first quarter 2022 operating and financial results.

"The FDA recently granted our request for a Type C meeting, which is expected to provide an important framework for interactions related to both the hold and our next proposed clinical trial," said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar. "There remains an urgent need for therapies that can slow or prevent the progression of Friedreich's ataxia, which remains the key motivating factor behind our clinical development efforts. We believe our Phase 1 data demonstrate proof-of-concept for CTI-1601 as a frataxin replacement therapy and its differentiated mechanism of action (MOA). We believe this MOA leaves CTI-1601 uniquely positioned to address the urgent need for disease modifying therapies in Friedreich's ataxia, as it is designed to address the root cause of this devastating disease. We look forward to its continued development and our upcoming interactions with the FDA."

CTI-1601 Update

In February 2022, Larimar received feedback from the U.S. Food and Drug Administration (FDA) regarding the May 2021 clinical hold placed on the CTI-1601 program. The May 2021 hold followed the Company's notification to the agency of mortalities which occurred at the highest dose levels in a 26-week non-human primate (NHP) toxicology study that was designed to support extended dosing of patients with CTI-1601. At the time the hold was placed, Larimar had no interventional clinical trials with patients enrolled or enrolling. In the feedback provided in February 2022, the FDA stated it was maintaining the clinical hold and that additional data are needed to resolve the clinical hold. This feedback followed Larimar's submission of a complete response to the agency. Larimar subsequently submitted a request for an FDA Type C meeting, which has been granted and has been scheduled for early in the third quarter of 2022. Throughout the course of the interactions associated with the Type C meeting, Larimar intends to work with the FDA to resolve the CTI-1601 clinical hold and agree on the study design and timing of its next proposed clinical trial. The Company plans to provide a regulatory update on CTI-1601 following receipt of the minutes from the scheduled Type C meeting with the FDA.

First Quarter 2022 Financial Results

As of March 31, 2022, the Company had cash and cash equivalents totaling $62.6 million which provides projected cash runway into the third quarter of 2023.

The Company reported a net loss for the first quarter of 2022 of $8.9 million, or $0.49 per share, compared to a net loss of $12.1 million, or $0.76 per share, for the first quarter of 2021.

Research and development expenses for the first quarter of 2022 were $5.8 million compared to $9.0 million for the first quarter of 2021. The decrease in research and development expenses compared to the prior year period was primarily driven by lower clinical supply manufacturing costs of $2.2 million and a decrease of $1.9 million in clinical trial costs, partially offset by an increase of $0.3 million in personnel related costs due to headcount additions in our research and development functions, higher non-clinical costs of $0.2 million, an increase of $0.2 million in professional fees primarily related to regulatory and clinical consulting services and an increase of $0.2 million in stock-based compensation expense associated with stock option grants made in 2021 and 2022.

General and administrative expenses for the first quarter of 2022 and the first quarter of 2021 were both $3.1 million. Increases in stock compensation expense associated with stock option grants that were made throughout 2021 and in the first quarter of 2022 and higher personnel costs were offset by lower recruiting and consulting fees.

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 statements regarding Larimar's expectations regarding its ability to resolve the clinical hold imposed by the FDA related to CTI-1601, 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 development plan and other matters regarding Larimar's business strategies, 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, Larimar’s ability to successfully engage with the FDA and satisfactorily respond to requests from the FDA for further information and data regarding CTI-1601, the timing and outcome of Larimar’s planned interactions with the FDA concerning the clinical hold on CTI-1601, the success, cost and timing of Larimar’s product development activities, nonclinical studies and clinical trials, including CTI-1601 clinical milestones; 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 ongoing impact of the COVID-19 pandemic on Larimar’s future clinical trials, manufacturing, regulatory and nonclinical study timelines, the ongoing impact of the COVID-19 pandemic and the potential impact of the Russian invasion of Ukraine on Larimar’s ability to raise additional capital 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 approval 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.

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.
Consolidated Balance Sheet
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 62,564	$ 70,097
Prepaid expenses and other current assets	2,315	2,107
Total current assets	64,879	72,204
Property and equipment, net	1,067	1,049
Operating lease right-of-use assets	3,270	3,406
Restricted cash	1,339	1,339
Other assets	668	669
Total assets	$ 71,223	$ 78,667
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 2,417	$ 1,660
Accrued expenses	5,840	6,592
Operating lease liabilities, current	616	594
Total current liabilities	8,873	8,846
Operating lease liabilities	5,245	5,408
Total liabilities	14,118	14,254
Commitments and contingencies (See Note 9)		
Stockholders’ equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of March 31, 2022 and December 31, 2021; no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 17,710,450 shares issued and outstanding as of March 31, 2022 and December 31, 2021	18	18
Additional paid-in capital	182,280	180,645
Accumulated deficit	(125,193)	(116,250)
Accumulated other comprehensive loss	—	—
Total stockholders’ equity	57,105	64,413
Total liabilities and stockholders’ equity	$ 71,223	$ 78,667

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 5,806	$ 8,974
General and administrative	3,081	3,132
Total operating expenses	8,887	12,106
Loss from operations	(8,887)	(12,106)
Other income, net	(56)	18
Net loss	$ (8,943)	$ (12,088)
Net loss per share, basic and diluted	$ (0.49)	$ (0.76)
Weighted average common shares outstanding, basic and diluted	18,338,853	15,996,133

Source: Larimar Therapeutics