Larimar Therapeutics Reports Fourth Quarter and Full Year 2022 Operating and Financial Results

March 14, 2023

- *First cohort of Larimar's Phase 2 dose exploration trial of CTI-1601 in participants with Friedreich's ataxia (FA) is fully enrolled and proceeding as planned*
- *Larimar expects to provide an update on the next steps of the Phase 2 trial in Q2 2023, after the FDA and independent data monitoring committee review data from the first cohort and provide feedback to the Company*
- *Top-line safety, pharmacokinetic, and pharmacodynamic (e.g., frataxin level) data from both of the Phase 2 trial's planned cohorts expected in 2H 2023*
- *Cash and investments of $118.4 million at December 31, 2022 provides projected cash runway into 2H 2024*

BALA CYNWYD, Pa., March 14, 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 fourth quarter and full year 2022 operating and financial results.

"Our recent progress provides a strong foundation for growth as we work to develop CTI-1601 as the first FA therapy designed to potentially address frataxin deficiency, which is the underlying cause of the disease," said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar. "The first cohort of our Phase 2 trial is fully enrolled, with an update that will outline the next steps for the trial anticipated in the second quarter. We also recently strengthened our balance sheet and leadership team with a financing and the appointment of long-time Johnson & Johnson veteran Dr. Gopi Shankar as our Chief Development Officer. Looking forward, we believe these accomplishments, together with our Phase 1 proof-of-concept data, leave us well positioned to build on our positive momentum as we seek to improve the therapeutic paradigm for patients with FA, who remain in need of a therapy that may address the root cause of the disease by increasing frataxin levels."

2022 and Subsequent Highlights

- Larimar recently completed enrollment in the 25 mg cohort of a Phase 2, four-week, placebo-controlled, dose exploration trial of CTI-1601 in participants with FA. The trial was cleared to begin enrollment in this first cohort in September 2022, when the U.S. Food and Drug Administration (FDA) lifted the full clinical hold previously placed on the CTI-1601 program and imposed a partial hold. The initiation of additional cohorts in the Phase 2 trial and/or the initiation of other clinical trials of CTI-1601 are contingent on a review of the Phase 2 trial's 25 mg cohort data by its independent data monitoring committee (IDMC) and the FDA. Larimar expects to provide an update on the next steps for the Phase 2 trial in Q2 2023, after it receives feedback from the FDA and IDMC on their review of data from the trial's 25 mg cohort. Top-line safety, pharmacokinetic, and pharmacodynamic (e.g., frataxin level) data from both cohorts of the Phase 2 trial are expected in 2H 2023.
- In September 2022, Larimar raised net proceeds of approximately $75.2 million through an underwritten offering of common stock, with Deerfield Management and other notable life science investors participating in the offering.
- In October 2022, Larimar announced the issuance of U.S. Patent No. 11,459,363, which provides composition of matter protection for CTI-1601 into at least July 2040.
- In February 2023, Larimar strengthened its leadership team with the appointment of Gopi Shankar, PhD, MBA, FAAPS, to the newly created position of Chief Development Officer. In this role, Dr. Shankar is responsible for the strategic development of Larimar's clinical and R&D programs. Dr. Shankar joined Larimar with more than 20 years of experience leading the development of novel biologics, most recently serving as Vice President and Global Head, Biologics Development Sciences at Janssen Research & Development (a pharmaceutical company of Johnson & Johnson, Inc.).

Fourth Quarter and Full Year 2022 Financial Results

As of December 31, 2022, the Company had cash, cash equivalents and marketable securities totaling $118.4 million.

The Company reported a net loss for the fourth quarter of 2022 of $9.4 million, or $0.21 per share, compared to a net loss of $9.1 million, or $0.50 per share, for the fourth quarter of 2021.

Research and development expenses for the fourth quarter of 2022 were $7.2 million compared to $6.3 million for the fourth quarter of 2021. The increase in research and development expenses compared to the prior year period was primarily driven by an increase of $1.8 million in clinical costs associated with the ongoing Phase 2 trial, an increase of $0.4 million in personnel expense, an increase of $0.3 million associated with the license milestone achievement in Q4 2022 and an increase of $0.1 million in non-cash, stock-based compensation expense associated with stock option

grants made in 2022, partially offset by a decrease of $0.5 million in drug manufacturing costs, a decrease of $0.4 million in consulting expenditures, a decrease of $0.4 million in nonclinical development costs and a decrease of $0.3 million in internal lab costs.

General and administrative expenses for the fourth quarter of 2022 were $3.2 million compared to $2.8 million for the fourth quarter of 2021. The increase in general and administrative expense was primarily driven by an increase of $0.2 million in legal fees associated with the new ATM agreement and patent work performed during Q4 2022, an increase of $0.2 million in personnel expense primarily associated with an employee severance agreement, partially offset by a decrease of $0.2 million in operational costs primarily related to technology and recruiting services.

For the full year 2022, the Company reported a net loss of $35.4 million, or $1.37 per share, compared to a net loss of $50.6 million, or $2.95 per share for the same period in 2021.

Research and development expenses for the full year 2022 were $24.3 million compared to $38.4 million for the same period in 2021. The decrease in research and development expenses was primarily driven by a decrease of $9.5 million in drug manufacturing costs, a decrease of $3.7 million in nonclinical development costs, a decrease of $1.6 million in clinical expense, a decrease of $0.9 million in consulting expenditures, and a decrease of $0.7 million in internal lab costs. These decreases were partially offset by an increase of $1.2 million in personnel expense, an increase of $0.7 million in non-cash, stock-based compensation expense associated with stock option grants made in 2021 and 2022 and an increase of $0.3 million in royalty fees associated with the milestone achieved in 2022.

General and administrative expenses for the full year 2022 were $12.2 million compared to $12.1 million for the same period in 2021. The increase in general and administrative expense was primarily driven by an increase of $0.5 million in stock-based compensation expense associated with stock option grants made in 2021 and 2022 and an increase of $0.5 million in personnel expense, partially offset by a decrease of $0.6 million in operational costs primarily related to technology and recruiting services and a decrease of $0.2 million in professional fees primarily associated with legal and consulting expense.

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 expectations regarding its ability to resolve the partial 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, 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, Larimar's ability to successfully engage with the FDA and satisfactorily respond to requests from the FDA for further information and data regarding the CTI-1601 clinical trial including the FDA review of data from cohort one from the Phase 2 dose exploration trial and FDA's agreement to escalate the dosing in cohort two, the timing and outcomes of Larimar's interactions with the FDA concerning the partial clinical hold, 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, 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.

Consolidated Balance Sheet
(unaudited)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 26,825	$ 70,097
Marketable securities	91,603	—
Prepaid expenses and other current assets	2,311	2,107
Total current assets	120,739	72,204
Property and equipment, net	831	1,049
Operating lease right-of-use assets	2,858	3,406
Restricted cash	1,339	1,339
Other assets	638	669
Total assets	$ 126,405	$ 78,667
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,686	$ 1,660
Accrued expenses	8,408	6,592
Operating lease liabilities, current	611	594
Total current liabilities	10,705	8,846
Operating lease liabilities	4,797	5,408
Total liabilities	15,502	14,254
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of December 31, 2022 and December 31, 2021; no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of December 31, 2022 and December 31, 2021; 43,269,200 and 17,710,450 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	43	18
Additional paid-in capital	262,496	180,645
Accumulated deficit	(151,605)	(116,250)
Accumulated other comprehensive loss	(31)	—
Total stockholders' equity	110,903	64,413
Total liabilities and stockholders' equity	$ 126,405	$ 78,667

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 7,218	$ 6,292	$ 24,250	$ 38,396
General and administrative	3,221	2,794	12,276	12,069
Total operating expenses	10,439	9,086	36,526	50,465
Loss from operations	(10,439)	(9,086)	(36,526)	(50,465)
Other income (expense), net	1,014	(48)	1,171	(171)
Net loss	$ (9,425)	$ (9,134)	$ (35,355)	$ (50,636)
Net loss per share, basic and diluted	$ (0.21)	$ (0.50)	$ (1.37)	$ (2.95)
Weighted average common shares outstanding, basic and diluted	43,897,603	18,338,853	25,761,394	17,164,284

Source: Larimar Therapeutics