Larimar Therapeutics Reports Third Quarter 2022 Operating and Financial Results

November 10, 2022

- *First cohort of Larimar's Phase 2 dose exploration trial of CTI-1601 in Friedreich's ataxia patients is ongoing and proceeding in line with the Company's planned timeline*
- *Larimar expects to provide an update on the Phase 2 trial in Q2 2023 and anticipates reporting top-line data from both cohorts in 2H 2023*
- *Cash of $124.7 million at September 30, 2022 provides projected cash runway into 2H 2024*

BALA CYNWYD, Pa., Nov. 10, 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 third quarter 2022 operating and financial results.

"This is an exciting time for Larimar, as we recently received regulatory clearance for CTI-1601's return to the clinic under a partial hold and completed a capital raise with a premier life science investor syndicate," said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar. "These important accomplishments allowed us to begin enrolling patients in the first cohort of our Phase 2 trial in Friedreich's ataxia patients, which continues to make progress. The trial's results are expected to inform CTI-1601's long-term dose regimen, thereby building upon the clinical proof-of-concept data generated in our Phase 1 program. We are grateful for the continued support we have received from the Friedreich's ataxia community and our shareholders over these past months and look forward to CTI-1601's continued development as a potentially disease-modifying therapy."

Third Quarter and Subsequent Highlights

- In September 2022, 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, thereby clearing the initiation of the 25 mg cohort of a Phase 2, four-week, placebo-controlled, dose exploration trial in Friedreich's ataxia (FA) patients. The study's 25 mg cohort is currently ongoing and proceeding in line with the Company's planned timeline. Additional cohorts and/or other clinical trials are contingent on a review of the study's 25 mg cohort data by the FDA and the data monitoring committee. Larimar expects to provide an update on the trial in Q2 2023 and anticipates reporting top-line data in 2H 2023.
- In September 2022, Larimar raised net proceeds of approximately $75.2 million through an underwritten offering of common stock. Deerfield Management and other notable life science investors participated 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.

Third Quarter 2022 Financial Results

As of September 30, 2022, the Company had cash and marketable securities totaling $124.7 million which provides projected cash runway into the second half of 2024.

The Company reported a net loss for the third quarter of 2022 of $8.3 million, or $0.37 per share, compared to a net loss of $16.8 million, or $0.92 per share, for the third quarter of 2021.

Research and development expenses for the third quarter of 2022 were $5.6 million compared to $14.0 million for the third quarter of 2021. The decrease in research and development expenses was primarily driven by a decrease of $6.7 million in drug manufacturing costs, a decrease of $1.0 million in nonclinical development costs, a decrease of $0.5 million in consulting expenditures, a decrease of $0.5 million in clinical expense partially offset by an increase of $0.4 million in personnel expense.

General and administrative expenses for the third quarter of 2022 were $2.9 million compared to $2.7 million for the third quarter of 2021. The increase in general and administrative expense was primarily driven by increases in professional fees associated with legal and accounting services and in personnel expense.

The Company reported a net loss for the nine months ended September 30, 2022 of $25.9 million, or $1.32 per share, compared to a net loss of $41.5 million, or $2.48 per share, for the nine months ended September 30, 2021.

Research and development expenses for the nine months ended September 30, 2022 were $17.0 million compared to $32.1 million for the nine months ended September 30, 2021. The decrease in research and development expenses was primarily driven by a decrease of $9.0 million in drug manufacturing costs, a decrease of $3.5 million in clinical trial expense, and a decrease of $3.3 million in nonclinical development costs.

General and administrative expenses for the nine months ended September 30, 2022 were $9.1 million compared to $9.3 million for the nine months ended September 30, 2021. The decrease in general and administrative expense was primarily driven by a decrease of $0.5 million in operational costs primarily related to technology and recruiting services and a decrease of $0.4 million in professional fees primarily associated with legal and consulting expense, partially offset by an increase of $0.5 million in stock-based compensation expense associated with stock option grants made in 2021 and 2022.

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, 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 86,047	$ 70,097
Marketable securities	38,652	—
Prepaid expenses and other current assets	2,428	2,107
Total current assets	127,127	72,204
Property and equipment, net	909	1,049
Operating lease right-of-use assets	2,997	3,406
Restricted cash	1,339	1,339
Other assets	643	669

Total assets	$ 133,015	$ 78,667
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 849	$ 1,660
Accrued expenses	7,939	6,592
Operating lease liabilities, current	632	594
Total current liabilities	9,420	8,846
Operating lease liabilities	4,933	5,408
Total liabilities	14,353	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 September 30, 2022 and December 31, 2021; no shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 43,269,200 shares and 17,710,450 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	43	18
Additional paid-in capital	260,839	180,645
Accumulated deficit	(142,180)	(116,250)
Accumulated other comprehensive loss	(40)	—
Total stockholders' equity	118,662	64,413
Total liabilities and stockholders' equity	$ 133,015	$ 78,667

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 5,582	$ 14,028	$ 17,032	$ 32,104
General and administrative	2,931	2,702	9,055	9,275
Total operating expenses	8,513	16,730	26,087	41,379
Loss from operations	(8,513)	(16,730)	(26,087)	(41,379)
Other income (expense), net	193	(75)	157	(123)
Net loss	$ (8,320)	$ (16,805)	$ (25,930)	$ (41,502)
Net loss per share, basic and diluted	$ (0.37)	$ (0.92)	$ (1.32)	$ (2.48)
Weighted average common shares outstanding, basic and diluted	22,228,228	18,287,924	19,649,558	16,768,458
Comprehensive loss:				
Net loss	$ (8,320)	$ (16,805)	$ (25,930)	$ (41,502)
Other comprehensive loss:				
Unrealized gain/(loss) on marketable debt securities	17	(1)	(40)	(1)
Total other comprehensive income (loss)	17	(1)	(40)	(1)
Total comprehensive loss	$ (8,303)	$ (16,806)	$ (25,970)	$ (41,503)

Source: Larimar Therapeutics