Larimar Therapeutics Reports Third Quarter 2021 Operating and Financial Results

November 12, 2021

BALA CYNWYD, Pa., Nov. 12, 2021 (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 and year to date September 30, 2021 operating and financial results.

“We are advancing towards 2022 with a strong balance sheet, the backing of high-quality institutional investors, and compelling Phase 1 data that demonstrate proof-of-concept for CTI-1601,” said Carole Ben-Maimon**,** MD, President and Chief Executive Officer of Larimar. “We continue to collect and analyze data from our 180-day non-human primate toxicology study so that we can continue moving towards the resolution of CTI-1601’s clinical hold and an expected return to the clinic in the first half of next year. We are working expeditiously towards this goal, as patients with Friedreich’s ataxia (FA) urgently need disease-modifying therapies. With a differentiated mechanism of action targeting the root cause of FA, we believe CTI-1601 is uniquely positioned to potentially address this need and look forward to its continued clinical development.”

Third Quarter 2021 Highlights

- Prior to the third quarter, the United States Food and Drug Administration (FDA) placed a clinical hold on the CTI-1601 clinical program after Larimar notified the agency of mortalities that occurred at the highest dose levels of a 180-day non-human primate (NHP) toxicology study designed to support extended dosing of patients with CTI-1601. In the clinical hold letter, the FDA stated that it needs a full study report from the NHP study and that Larimar may not initiate additional clinical trials until the Company has submitted the report and received notification from the agency that additional clinical trials may commence. At the time of the notice, the Company had no interventional clinical trials with patients enrolled or enrolling.

  In July 2021, Larimar completed dosing in the 180-day NHP toxicology study, and it continues to collect and analyze data. While there is no way to predict the FDA’s response (which the Company anticipates will not be received prior to the first quarter of 2022) or whether they will require additional data or testing before lifting the clinical hold on CTI-1601 in full or in part, the Company expects to initiate its Jive open-label extension and pediatric multiple ascending dose trials in the first half of next year.

- Under an Equity Distribution Agreement with an investment bank, the Company may sell up to an aggregate of $50 million of shares of common stock from time to time in connection with an “at the market” program. In July 2021, the Company sold 2,342,720 shares under the agreement for net proceeds of $19.9 million. As of September 30, 2021 and the date of this announcement, $29.2 million of common stock remains available for sale under this program.
- In August 2021, Larimar initiated a non-interventional healthy volunteer study designed to generate data for comparison to patients with FA.

Third Quarter 2021 Financial Results

As of September 30, 2021, the Company had cash, cash equivalents and marketable debt securities totaling $78.0 million.

The Company reported a net loss for the third quarter of 2021 of $16.8 million, or $0.92 per share, compared to a net loss of $10.3 million, or $0.64 per share, for the third quarter of 2020.

Research and development expenses for the third quarter of 2021 were $14.0 million compared to $6.9 million for the third quarter of 2020. The increase in research and development expenses compared to the prior year period was primarily driven by higher clinical supply manufacturing costs of $6.4 million, higher non-clinical and internal laboratory costs of $1.3 million, an increase of $0.3 million in personnel related costs due to headcount additions in our research and development functions, and an increase of $0.3 million in stock-based compensation expense associated with stock option grants made in the second half of 2020 and thus far in 2021, partially offset by a decrease of $1.4 million in clinical trial costs.

General and administrative expenses for the third quarter of 2021 were $2.7 million compared to $3.4 million for the third quarter of 2020. The decrease in general and administrative expenses as compared to the prior year period was primarily driven by a decrease of $1.1 million in professional fees primarily associated with accounting, legal and consulting fees partially offset by an increase of $0.8 million in stock-based compensation expense associated with stock option grants made in the second half of 2020 and thus far in 2021. General and administrative expenses for the third quarter of 2020 included costs associated with the Company’s May 2020 reverse merger with Zafgen, Inc. (the Merger)

For the nine-months ended September 30, 2021, the Company reported a net loss of $41.5 million, or $2.48 per share, compared to a net loss of $28.3 million, or $2.69 per share for the same period in 2020.

Research and development expenses for the nine-months ended September 30, 2021 were $32.1 million compared to $20.8 million for the same period in 2020. The increase in research and development expenses compared to the prior year period was primarily driven by higher clinical supply manufacturing costs of $4.5 million, higher non-clinical and internal laboratory costs of $2.9 million, an increase of $1.7 million in personnel related costs due to increased headcount in our research and development functions, an increase of $1.1 million in stock-based compensation expense associated with stock option grants made in the second half of 2020 and thus far in 2021, and an increase of $0.9 million in clinical trial costs.

General and administrative expenses for the nine-months ended September 30, 2021 were $9.3 million compared to $7.6 million for the same period in 2020. The increase in general and administrative expenses as compared to the prior year period was primarily driven by an increase of $1.8 million in stock-based compensation expense associated with stock option grants made in the second half of 2020 and thus far in 2021, and an increase of $1.2 million in costs required to function as a public company (nine months as a publicly-held company in 2021 compared to four months as a publicly-held company in 2020), an increase of $0.5 million in personnel related costs due to increased headcount, partially offset by a decrease of $1.4 million in professional fees primarily associated with accounting, legal and consulting fees. General and administrative expenses for the nine months ended September 30,2020 included costs associated with the Merger.

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 currently being evaluated in a Phase 1 clinical program in the U.S. 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 Larimar's expectation that it will be able to initiate its Jive open-label extension and pediatric multiple ascending dose trials in the first half of 2022, 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 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 clinical trials, and assessments; the ongoing impact of the COVID-19 pandemic on Larimar's future clinical trials, manufacturing, regulatory and nonclinical study timelines, 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.

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Larimar Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 71,525	$ 68,148
Marketable debt securities	6,499	24,490
Prepaid expenses and other current assets	3,229	5,314
Total current assets	81,253	97,952
Property and equipment, net	1,135	1,040
Operating lease right-of-use assets	3,540	3,936

Restricted cash	1,339	1,339
Other assets	671	419
Total assets	$ 87,938	$ 104,686
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,766	$ 2,634
Accrued expenses	7,966	5,843
Operating lease liabilities, current	574	515
Total current liabilities	10,306	8,992
Operating lease liabilities	5,565	6,002
Total liabilities	15,871	14,994
Commitments and contingencies (See Note 9)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of September 30, 2021 and December 31, 2020; no shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 17,710,450 and 15,367,730 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	18	15
Additional paid-in capital	179,165	155,290
Accumulated deficit	(107,116)	(65,614)
Accumulated other comprehensive loss	—	1
Total stockholders' equity	72,067	89,692
Total liabilities and stockholders' equity	$ 87,938	$ 104,686

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

	Nine Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 14,028	$ 6,919	$ 32,104	$ 20,833
General and administrative	2,702	3,416	9,275	7,575
Total operating expenses	16,730	10,335	41,379	28,408
Loss from operations	(16,730)	(10,335)	(41,379)	(28,408)
Other income (expense), net	(75)	61	(123)	130
Net loss	$ (16,805)	$ (10,274)	$ (41,502)	$ (28,278)
Net loss per share, basic and diluted	$ (0.92)	$ (0.64)	$ (2.48)	$ (2.69)
Weighted average common shares outstanding, basic and diluted	18,287,924	15,984,609	16,768,458	10,505,826

Source: Larimar Therapeutics