UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 14, 2022

Larimar Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36510**	**20-3857670**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Three Bala Plaza East, Suite 506
Bala Cynwyd, Pennsylvania **19004**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code: (844) 511-9056

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**LRMR**	**Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On February 14, 2022, Larimar Therapeutics, Inc. (the "***Company***") issued a press release providing an update on the Company's CTI-1601 clinical program. A copy of this press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Below is a list of exhibits included with this Current Report on Form 8-K.

Exhibit No.	Document
99.1	Press Release of Larimar Therapeutics, Inc., dated February 14, 2022*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Larimar Therapeutics, Inc.

By: /s/ Carole S. Ben-Maimon, M.D.
Name: Carole S. Ben-Maimon, M.D.
Title: President and Chief Executive Officer

Date: February 14, 2022

Exhibit 99.1

Larimar Therapeutics Provides Update on CTI-1601 Clinical Program

Bala Cynwyd, PA, February 14, 2022 – Larimar Therapeutics, Inc. ("Larimar") (Nasdaq: LRMR), a clinical-stage biotechnology company focused on developing treatments for complex rare diseases, today announced that it has received feedback from the U.S. Food and Drug Administration (FDA) regarding the clinical hold on Larimar's CTI-1601 program. FDA stated it is maintaining its clinical hold at this time and that additional data is needed to resolve the clinical hold. Larimar is further analyzing previously completed studies, and is evaluating if additional studies are warranted. The Company also intends to engage FDA to determine how best to provide these data. Larimar is currently reassessing guidance on the timing of the planned Jive open-label extension and pediatric multiple-ascending dose clinical trials as it works to meet the agency's request.

"Patient safety is our top priority," said Carole Ben-Maimon**,** MD, President and Chief Executive Officer of Larimar. "Our next step is to engage with the agency to determine how we can meet their request in the most efficient and expeditious manner. Based on all available clinical and non-clinical data, we continue to believe there is a path forward through the resolution of the CTI-1601 clinical hold. We have a robust Phase 1 dataset, which demonstrates 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 (FA), as it is designed to address the root cause of this devastating disease. We remain committed to CTI-1601's further development and are working towards this goal with a strong cash position which provides runway at least into 2023. We intend to operate under a cost reduction plan while resolving the clinical hold to manage burn and extend our cash runway if needed."

The CTI-1601 program was placed on a clinical hold by the FDA following 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 of the notice, Larimar had no interventional clinical trials with patients enrolled or enrolling. The recent feedback from the FDA follows Larimar's submission of a complete response including a comprehensive study report from the 26-week NHP toxicology study.

Data from the Phase 1 single- and multiple-ascending dose (MAD) clinical trials indicated that repeated subcutaneous injections of CTI-1601 were generally well tolerated at doses up to 100 mg administered daily for up to 13 days. No serious adverse events, important medical events, or treatment-related severe adverse events were reported in the trial and the number and severity of adverse events did not increase with increasing exposure to CTI-1601. The most common adverse events were mild and moderate injection site reactions. Data from the MAD trial also showed that daily subcutaneous injections of CTI-1601 at doses of 50 mg or 100 mg resulted in frataxin levels in peripheral tissues (buccal cells) that were at or in excess of those that would be expected in phenotypically normal heterozygous carriers.

About CTI-1601

CTI-1601 is a recombinant fusion protein intended to deliver human frataxin into the mitochondria of patients with Friedreich's ataxia who are unable to produce enough of this essential protein. CTI-1601 has been granted Rare Pediatric Disease designation, Fast Track designation and Orphan Drug designation by the U.S. Food and Drug Administration (FDA), Orphan Drug Designation by the European Commission, and PRIME designation by the European Medicines Agency.

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 Larimar's expectation as to when it will be able to initiate its Jive open-label extension and pediatric multiple ascending dose trials, and other matters regarding Larimar's business strategies, use of capital, projected cash runway, 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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