
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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): March 4, 2021

Larimar Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36510
(Commission
File Number)

20-3857670
(I.R.S. Employer
Identification No.)

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

19004
(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 2.02 Results of Operations and Financial Condition

On March 4, 2021, Larimar Therapeutics, Inc. (the “**Company**”) announced its financial results and operational highlights for the fourth quarter of 2020 and for the year ended December 31, 2020. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

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

<u>Exhibit No.</u>	<u>Document</u>
99.1	Press Release issued by Larimar Therapeutics, Inc. on March 4, 2021*

* Furnished 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, thereunto 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: March 4, 2021



Larimar Therapeutics Reports Fourth Quarter and Full Year 2020 Operating and Financial Results

- Reported preliminary Phase 1 findings from a Single Ascending Dose (SAD) trial that suggest single subcutaneous injections of CTI-1601 were well tolerated at doses up to 100 mg in Friedreich's ataxia (FA) patients

- Placebo-controlled Phase 1 trials in FA patients remain on track for topline data in Q2 2021

- Cash and investments of \$92.6 million as of December 31, 2020

Bala Cynwyd, PA, March 4, 2021 – 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 2020 operating and financial results.

"2020 was a transformational year for Larimar as we entered the public market, built a strong institutional shareholder base, and reported initial clinical findings in our lead Friedreich's ataxia (FA) program," said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar. "These accomplishments were enabled by the talent and commitment of our team, who successfully navigated the challenges of the pandemic to execute on our goals without compromising patient safety. We are thankful for their work and for the dedication of the patients who participated in our clinical trials and the Friedreich's Ataxia Research Alliance, all of whom were key components of our recent progress."

Dr. Ben-Maimon continued, "Looking ahead to 2021, we believe we are poised to achieve critical milestones in the development of CTI-1601 as a frataxin replacement therapy. We recently completed dosing of the third cohort in our placebo-controlled multiple-ascending dose (MAD) trial and expect to report topline data from both this study and our placebo-controlled single- ascending dose (SAD) study in the second quarter. These data will provide key insights into CTI-1601's safety and tolerability, as well as into the frataxin levels achieved in patients administered CTI-1601 at the evaluated doses and dosing regimens. We remain on track to initiate our open-label extension, the JIVE trial, and a pediatric MAD trial in FA patients during the second half of the year, which will allow us to further advance CTI-1601's development. We believe the sustained progress of these clinical programs, combined with the continued execution of our corporate milestones, will position us to generate stakeholder value as we advance toward our goal of addressing the unmet needs of FA patients."

2020 and Subsequent Highlights

- In May 2020, Larimar announced the completion of the reverse merger between Chondrial Therapeutics, Inc. and Zafgen, Inc. The combined, publicly traded clinical-stage biotechnology company began operating under the name Larimar Therapeutics, Inc. and its shares commenced trading on the Nasdaq Global Market on May 29, 2020, under the ticker symbol "LRMR."

- In May 2020, Larimar completed a private placement of common stock and pre-funded warrants to purchase common stock for \$80 million of gross proceeds before placement agent fees and expenses.
- In August 2020, the European Commission granted an orphan drug designation for CTI-1601 for the treatment of FA. This designation complements previously received Orphan Drug, Fast Track, and Rare Pediatric Disease designations from the U.S. Food and Drug Administration.
- In December 2020, Larimar announced the completion of dosing in its SAD clinical trial in FA patients. Preliminary data from the SAD trial suggest that single subcutaneous injections of CTI-1601 were well tolerated at doses up to 100 mg.
- Larimar recently completed dosing of the third cohort of its double-blind, placebo-controlled, MAD clinical trial. Topline data from both the SAD and MAD trials are expected in Q2 2021.

Fourth Quarter and Full Year 2020 Financial Results

As of December 31, 2020, the Company had cash, cash equivalents, and marketable debt securities totaling \$92.6 million.

The Company reported a net loss for the fourth quarter of 2020 of \$14.2 million, or \$0.89 per share, compared to a net loss of \$6.1 million, or \$1.00 per share, for the fourth quarter of 2019.

Research and development expenses for the fourth quarter of 2020 were \$10.6 million compared to \$5.4 million for the fourth quarter of 2019. The increase in research and development expenses compared to the prior year period was primarily driven by higher clinical supply manufacturing costs, an increase in clinical trial costs, an increase in personnel related costs due to headcount additions in our research and development functions and an increase in stock compensation expense associated with stock option grants made in 2020.

General and administrative expenses for the fourth quarter of 2020 were \$3.8 million, compared to \$0.8 million for the fourth quarter of 2019. The increase in general and administrative expenses as compared to the prior year period was primarily driven by an increase in professional fees and insurance costs that are primarily due to the costs of operating as a public company, an increase in personnel related costs due to increased headcount, and an increase in stock-based compensation associated with stock option grants made in 2020.

For the full year 2020, the Company reported a net loss of \$42.5 million, or \$3.57 per share, compared to a net loss of \$23.1 million, or \$3.80 per share for the same period in 2019.

Research and development expenses for the full year 2020 were \$31.4 million compared to \$20.8 million for the same period in 2019. The increase in research and development expenses compared to the prior year period was primarily driven by higher clinical supply manufacturing costs, an increase in clinical trial costs, an increase in personnel related costs due to headcount additions in our research and development functions and an increase in stock compensation expense associated with stock option grants made in 2020 partially offset by a decrease in toxicology studies costs.

General and administrative expenses for the full year 2020 were \$11.4 million, compared to \$2.4 million for the same period in 2019. The increase in general and administrative expenses as compared to the prior year period was primarily driven by an increase in professional fees and insurance costs that are primarily due to the costs of operating as a public company, an increase in personnel related costs due to increased headcount, and an increase in stock-based compensation associated with stock option grants made in 2020.

About Larimar Therapeutics

Larimar Therapeutics, Inc. (Nasdaq: LRMR), is a clinical-stage biotechnology company focused on developing treatments for complex rare diseases. The company's lead compound, CTI-1601, is currently being evaluated in a Phase 1 clinical program in the U.S. as a potential treatment for FA. 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 ability to develop and commercialize CTI-1601 and other planned product candidates, Larimar's planned research and development efforts, 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, the success, cost and timing of Larimar's product development activities, studies and clinical trials, including CTI-1601 clinical milestones; the ongoing impact of the COVID-19 pandemic on Larimar's clinical trial, manufacturing, regulatory and nonclinical study timelines, ability to raise additional capital and general economic conditions; Larimar's ability 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 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 the Company 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 views 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)

	<u>December 31,</u> 2020	<u>December 31,</u> 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 68,148	\$ 1,009
Marketable debt securities	24,490	—
Prepaid expenses and other current assets	5,314	3,741
Total current assets	97,952	4,750
Property and equipment, net	1,040	274
Operating lease right-of-use assets	3,936	87
Restricted cash	1,339	—
Other assets	419	90
Total assets	<u>\$ 104,686</u>	<u>\$ 5,201</u>
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,634	\$ 3,539
Accrued expenses	5,843	2,259
Operating lease liabilities, current	515	97
Total current liabilities	8,992	5,895
Operating lease liabilities	6,002	—
Total liabilities	<u>14,994</u>	<u>5,895</u>
Commitments and contingencies (See Note 9)		
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of December 31, 2020 and December 31, 2019; no shares issued and outstanding as of December 31, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 15,367,730 and 6,091,250 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	15	6
Additional paid-in capital	155,290	22,432
Accumulated deficit	(65,614)	(23,132)
Accumulated other comprehensive gain	1	—
Total stockholders' equity (deficit)	<u>89,692</u>	<u>(694)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 104,686</u>	<u>\$ 5,201</u>

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	\$ 10,563	\$ 5,406	\$ 31,407	\$ 20,790
General and administrative	3,832	751	11,397	2,424
Total operating expenses	<u>14,395</u>	<u>6,157</u>	<u>42,804</u>	<u>23,214</u>
Loss from operations	(14,395)	(6,157)	(42,804)	(23,214)
Other income, net	192	82	322	82
Net loss	<u>\$ (14,203)</u>	<u>\$ (6,075)</u>	<u>\$ (42,482)</u>	<u>\$ (23,132)</u>
Net loss per share, basic and diluted	<u>\$ (0.89)</u>	<u>\$ (1.00)</u>	<u>\$ (3.57)</u>	<u>\$ (3.80)</u>
Weighted average common shares outstanding, basic and diluted	<u>15,985,199</u>	<u>6,091,250</u>	<u>11,883,106</u>	<u>6,091,250</u>