

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

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2021

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number 001-36510

LARIMAR THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

20-3857670
(IRS Employer
Identification No.)

19004
(zip code)

(844) 511-9056

(Registrant's telephone number, including area code)

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	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Emerging growth company	<input type="checkbox"/>
Smaller reporting company	<input checked="" type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 10, 2021, there were 17,710,450 shares of the registrant's Common Stock, \$0.001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q that are not statements of historical or current facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “positioned,” “potential,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that “we believe” or similar statements reflect our beliefs and opinions on the relevant subject. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- our ability to successfully engage with the FDA concerning the clinical hold on the investigational new drug application (IND) for CTI-1601 and the timing and outcomes of our planned interactions with the FDA and submission of a clinical hold complete response with further information and data regarding CTI-1601 requested by FDA to lift the clinical hold and allow initiation of interventional clinical studies;
 - our estimates regarding future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing;
 - how long we can continue to fund our operations with our existing cash, cash equivalents and marketable debt securities;
 - our ability to optimize and scale CTI-1601 or any other product candidate’s manufacturing process and to manufacture sufficient quantities of clinical and, if approved, commercial supplies of CTI-1601;
 - our ability to realize any value from CTI-1601 and any other product candidate we may develop in the future in light of inherent risks and difficulties involved in successfully bringing product candidates to market and the risk that products will not achieve broad market acceptance;
 - delays or changes in our anticipated clinical timelines, including as a result of patient recruitment, clinical and non-clinical results, changes in clinical protocols and milestones for CTI-1601, including those associated with COVID-19;
 - uncertainties in obtaining successful non-clinical or clinical trial results that reliably and meaningfully demonstrate safety, tolerability and efficacy profiles that are satisfactory to the FDA, EMA, and other comparable regulatory authorities for marketing approval for CTI-1601 or any other product candidate that we may develop in the future and unexpected costs that may result therefrom;
 - our ability to comply with regulatory requirements applicable to our business and other regulatory developments in the United States and foreign countries;
 - uncertainties associated with the clinical development and regulatory approval for CTI-1601 or any other product candidate that we may develop in the future, including potential delays in the commencement, enrollment, and completion of clinical trials;
 - the difficulties and expenses associated with obtaining and maintaining regulatory approval for CTI-1601 or any other product candidate we may develop in the future, and the indication and labeling under any such approval;
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- the size and growth of the potential markets for CTI-1601 or any other product candidate that we may develop in the future, the rate and degree of market acceptance of CTI-1601 or any other product candidate that we may develop in the future and our ability to serve those markets;
- the success of competing therapies and products that are or become available;
- our ability to obtain and maintain patent protection and defend our intellectual property rights against third parties;
- the performance of third parties upon which we depend, including third-party CROs, and third-party suppliers, manufacturers, distributors, and logistics providers;
- our ability to maintain our relationships, and contracts with our key vendors;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- our ability to maintain proper functionality and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption; and
- the extent to which health epidemics and other outbreaks of communicable diseases, including the ongoing COVID-19 pandemic, disrupt our operations, the operations of third parties on which we rely or the operations of regulatory agencies we interact with in the development of CTI-1601.

These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe the expectations reflected in the forward-looking statements are reasonable, the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements may not be achieved or occur at all. The factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K filed on March 4, 2021 and subsequent reports on Form 10-Q filed thereafter. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of any unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

Larimar Therapeutics, Inc.

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Signatures

As previously disclosed, on May 28, 2020, Zafgen, Inc., a Delaware corporation (“Zafgen”), completed a Merger with Chondrial Therapeutics, Inc., a Delaware corporation (“Chondrial”), in accordance with the terms of the Agreement and Plan of Merger (the “Merger Agreement”) entered into on December 17, 2019. Pursuant to the Merger Agreement, (i) a subsidiary of Zafgen merged with and into Chondrial, with Chondrial continuing as a wholly owned subsidiary of Zafgen and the surviving corporation of the merger and (ii) Zafgen was renamed as “Larimar Therapeutics, Inc.” (the “Merger”).

For accounting purposes, the Merger is treated as a “reverse asset acquisition” under generally accepted accounting principles in the United States (“U.S. GAAP”) and Chondrial is considered the accounting acquirer. Accordingly, Chondrial’s historical results of operations replace Larimar’s historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company are included in the Company’s financial statements.

Unless the context otherwise requires, references to the “Company,” the “combined company” “we,” “our” or “us” in this report refer to Larimar Therapeutics, Inc. and its subsidiaries, references to “Larimar” refer to the Company following the completion of the Merger, and references to “Zafgen” refer to the Company prior to the completion of the Merger.

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 70,630	\$ 68,148
Marketable debt securities	—	24,490
Prepaid expenses and other current assets	3,406	5,314
Total current assets	74,036	97,952
Property and equipment, net	1,211	1,040
Operating lease right-of-use assets	3,673	3,936
Restricted cash	1,339	1,339
Other assets	672	419
Total assets	<u>\$ 80,931</u>	<u>\$ 104,686</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,463	\$ 2,634
Accrued expenses	5,675	5,843
Operating lease liabilities, current	553	515
Total current liabilities	7,691	8,992
Operating lease liabilities	5,715	6,002
Total liabilities	<u>13,406</u>	<u>14,994</u>
Commitments and contingencies (See Note 9)		
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of June 30, 2021 and December 31, 2020; no shares issued and outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 15,367,730 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	15	15
Additional paid-in capital	157,820	155,290
Accumulated deficit	(90,311)	(65,614)
Accumulated other comprehensive loss	1	1
Total stockholders' equity	<u>67,525</u>	<u>89,692</u>
Total liabilities and stockholders' equity	<u>\$ 80,931</u>	<u>\$ 104,686</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 9,102	\$ 8,907	\$ 18,076	\$ 13,914
General and administrative	3,441	2,492	6,573	4,159
Total operating expenses	12,543	11,399	24,649	18,073
Loss from operations	(12,543)	(11,399)	(24,649)	(18,073)
Other income (expense), net	(66)	69	(48)	69
Net loss	\$ (12,609)	\$ (11,330)	\$ (24,697)	\$ (18,004)
Net loss per share, basic and diluted	\$ (0.79)	\$ (1.21)	\$ (1.54)	\$ (2.33)
Weighted average common shares outstanding, basic and diluted	15,996,133	9,381,412	15,996,133	7,736,331
Comprehensive loss:				
Net loss	\$ (12,609)	\$ (11,330)	\$ (24,697)	\$ (18,004)
Other comprehensive loss:				
Unrealized gain (loss) on marketable debt securities	—	(3)	—	(3)
Total other comprehensive loss	—	(3)	—	(3)
Total comprehensive loss	\$ (12,609)	\$ (11,333)	\$ (24,697)	\$ (18,007)

The accompanying notes are an integral part of these condensed consolidated financial statements.

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN
STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Par Value				
Balances as of December 31, 2020	15,367,730	\$ 15	\$ 155,290	\$ (65,614)	\$ 1	\$ 89,692
Stock-based compensation expense	—	—	1,180	—	—	1,180
Net loss	—	—	—	(12,088)	—	(12,088)
Balances as of March 31, 2021	15,367,730	\$ 15	\$ 156,470	\$ (77,702)	\$ 1	\$ 78,784
Stock-based compensation expense	—	—	1,350	—	—	1,350
Net loss	—	—	—	(12,609)	—	(12,609)
Balances as of June 30, 2021	15,367,730	\$ 15	\$ 157,820	\$ (90,311)	\$ 1	\$ 67,525

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Par Value				
Balances as of December 31, 2019	6,091,250	\$ 6	\$ 22,432	\$ (23,132)	\$ —	\$ (694)
Capital contributions from related party	—	—	9,595	—	—	9,595
Stock-based compensation expense	—	—	29	—	—	29
Net loss	—	—	—	(6,674)	—	(6,674)
Balances as of March 31, 2020	6,091,250	\$ 6	\$ 32,056	\$ (29,806)	\$ —	\$ 2,256
Capital contributions from related party	—	—	8,400	—	—	8,400
Merger with Zafgen Inc.	3,124,337	3	37,116	—	—	37,119
Private Placement of common shares and pre-funded warrants, net of transaction costs	6,140,619	6	75,344	—	—	75,350
Stock-based compensation expense	—	—	752	—	—	752
Unrealized loss on marketable debt securities	—	—	—	—	(3)	(3)
Net loss	—	—	—	(11,330)	—	(11,330)
Balances as of June 30, 2020	15,356,206	\$ 15	\$ 153,668	\$ (41,136)	\$ (3)	\$ 112,544

The accompanying notes are an integral part of these condensed consolidated financial statements.

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (24,697)	\$ (18,004)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,530	781
Loss on disposal of fixed asset	5	—
Depreciation expense	150	55
Amortization of premium on marketable securities	(11)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,908	(1,760)
Accounts payable	(1,466)	(3,284)
Accrued expenses	(168)	1,067
Right-of-use assets	263	89
Operating lease liabilities	(249)	(85)
Other assets	(253)	21
Net cash used in operating activities:	<u>(21,988)</u>	<u>(21,120)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(31)	(58)
Purchase of marketable securities	(1,749)	—
Maturities and sales of marketable securities	26,250	—
Cash, cash equivalents, and restricted cash acquired in connection with the Merger	—	41,934
Merger transaction costs	—	(1,233)
Net cash provided by investing activities	<u>24,470</u>	<u>40,643</u>
Cash flows from financing activities:		
Capital contribution from related party	—	17,995
Proceeds from sale of common stock and prefunded warrants, net of issuance costs	—	75,485
Net cash provided by financing activities	<u>—</u>	<u>93,480</u>
Net increase in cash, cash equivalents and restricted cash	2,482	113,003
Cash, cash equivalents and restricted cash at beginning of period	69,487	1,009
Cash, cash equivalents and restricted cash at end of period	<u>\$ 71,969</u>	<u>\$ 114,012</u>
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of net assets acquired in the Merger, including \$1.0 million of marketable debt securities and excluding cash acquired	\$ —	\$ (4,815)
Property and equipment included in accounts payable and accrued expenses	\$ 295	\$ —
Offering costs included in accounts payable and accrued expense	\$ —	\$ 135
Merger transaction costs included in accounts payable and accrued expenses	\$ —	\$ 65
Leased assets obtained in exchange for new operating lease liabilities	\$ —	\$ 448

The accompanying notes are an integral part of these condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)**1. Organization, Clinical Development, Nature of the Business, COVID-19 Risk and Basis of Presentation**

Larimar Therapeutics, Inc., together with its subsidiaries (the “Company” or “Larimar”), is a clinical-stage biotechnology company focused on developing treatments for patients suffering from complex rare diseases using its novel cell penetrating peptide technology platform. Larimar’s lead product candidate, CTI-1601, is a subcutaneously administered, recombinant fusion protein intended to deliver human frataxin, or FXN, an essential protein, to the mitochondria of patients with Friedreich’s ataxia. Friedreich’s ataxia is a rare, progressive, and fatal disease in which patients are unable to produce sufficient FXN due to a genetic abnormality.

In May 2021, Larimar reported positive topline data from its Phase 1 Friedreich’s ataxia (FA) program after completing dosing of the single ascending dose (SAD) trial in December 2020 and of the multiple ascending dose (MAD) trial in March 2021. Data from these trials demonstrate proof-of-concept by showing that daily subcutaneous injections of CTI-1601 for up to 13 days resulted in dose-dependent increases in frataxin levels from baseline compared to placebo in all evaluated tissues (buccal cells, skin, and platelets). Frataxin levels achieved in peripheral tissues (buccal cells) following daily 50 mg and 100 mg subcutaneous injections of CTI-1601 were at or in excess of frataxin levels that would be expected in phenotypically normal heterozygous carriers. There were no serious adverse events (SAEs) associated with either the MAD or SAD trials.

On May 25, 2021 the United States Food and Drug Administration (FDA) placed a clinical hold on the CTI-1601 clinical program following the Company’s notification to the FDA of mortalities which occurred at the highest dose levels in an ongoing 180-day non-human primate (NHP) toxicology study, which is 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 ongoing NHP study and Larimar may not initiate additional clinical trials until the company has submitted the report and received notification from the FDA that additional clinical trials may commence. At the time of this notice, the Company had no interventional clinical trials with patients enrolled or enrolling.

In July 2021, the Company completed dosing in the non-human primate toxicology study discussed above. The Company is currently collecting and analyzing data from the study. While there is no way to predict the FDA’s response 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 MAD trials in the first half of next year.

The Company is subject to risks and uncertainties common to pre-commercialization companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with governmental regulations, failure to secure regulatory approval for its drug candidates or any other product candidates and the ability to secure additional capital to fund operations. Drug candidates currently under development will require extensive non-clinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of Coronavirus, a global pandemic. The pandemic resulted in the temporary stoppage of the Company’s CTI-1601 Phase 1 clinical trials in patients with Friedreich’s ataxia in March 2020. In July 2020, the Company resumed these clinical trials, and have since completed dosing of both its single ascending dose and multiple ascending dose clinical trials. Vaccines manufactured by Moderna, Pfizer and Johnson & Johnson were introduced late in the fourth quarter of 2020 and became widely available by the end of the first quarter of 2021. While the vaccines have proven effective in reducing the severity and mortality of COVID-19 including the variants that have evolved to date, the overall vaccination rate in the United States has not reached the level required for herd immunity in some states, particularly in some areas of the country. The incidence of variants of COVID-19, has been increasing particularly among unvaccinated individuals and the variant is proving to be more easily spread than earlier variants. The low vaccination rate, the spread of variants, the evolution of furthermore deadly mutations against which the current vaccines may prove ineffective could again result in major disruptions to businesses and markets worldwide. The

Company's business, results of operations, financial condition and cash flows could be materially and adversely affected. Specifically, the Company could experience additional delays in future clinical trial timelines as a result of additional travel and hospital restrictions related to the COVID-19 pandemic which may be imposed or experience supply shortages or manufacturer shutdowns impacting the manufacture of drug substance or drug product. The financial statements do not reflect any adjustments as a result of the pandemic.

Merger with Zafgen

On December 17, 2019, Zafgen, Inc. ("Zafgen"), Chondrial Therapeutics Inc. ("Chondrial"), Zordich Merger Sub, Inc. ("Merger Sub") and Chondrial Holdings, LLC ("Holdings"), the sole stockholder of Chondrial, entered into an Agreement and Plan of Merger, as amended on March 9, 2020 (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Chondrial, with Chondrial surviving as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the "Merger").

The transaction was accounted for as a reverse acquisition in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, Chondrial was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the facts that, immediately following the Merger: (1) former shareholders of Chondrial own a substantial majority of the voting rights of the combined company; (2) the majority of the board of directors of the combined company is composed of directors designated by Chondrial under the terms of the Merger Agreement; and (3) existing members of Chondrial management constituted the management of the combined company. Because Chondrial has been determined to be the accounting acquirer in the Merger, but not the legal acquirer, the Merger is deemed a reverse acquisition under the guidance of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*. As a result, the historical financial statements of Chondrial are the historical financial statements of the combined company. As the Merger has been accounted for as an asset acquisition, goodwill has not been recorded within the condensed combined balance sheet.

The Merger was completed on May 28, 2020 pursuant to the terms of the Merger Agreement. In addition, immediately prior to the closing of the Merger, Zafgen effected a 1-for-12 reverse stock split (the "Reverse Stock Split") of Zafgen's common stock, par value \$0.001 per share (the "Zafgen Common Stock"). At the effective time of the Merger (the "Effective Time"), each share of Chondrial's common stock, par value \$0.001 per share ("Chondrial Common Stock"), outstanding immediately prior to the Effective Time was converted into the right to receive shares of Zafgen Common Stock based on an exchange ratio set forth in the Merger Agreement. At the Effective Time following the Reverse Stock Split, the exchange ratio was determined to be 60,912.5005 shares of Zafgen Common Stock for each share of Chondrial Common Stock (the "Exchange Ratio"). At the closing of the Merger on May 28, 2020, Zafgen issued an aggregate of 6,091,250 shares of its common stock to Holdings (the "Merger Shares"), based on the Exchange Ratio after giving effect to the Reverse Stock Split described below. Holdings subsequently distributed the Merger Shares to its members.

In addition, all outstanding options exercisable for common units of Holdings became options exercisable for the shares of common stock of Zafgen based on the conversion factor discussed within the Merger Agreement. In connection with the Merger, Zafgen changed its name to Larimar Therapeutics, Inc. Following the closing of the Merger, Chondrial Therapeutics, Inc. became a wholly owned subsidiary of the Company. In December 2020, Chondrial Therapeutics was legally merged into Larimar Therapeutics, Inc. As used herein, the words "the Company" refers to, for periods following the Merger, Larimar, together with its subsidiaries, and for periods prior to the Merger, Chondrial Therapeutics Inc., and its direct and indirect subsidiaries, as applicable.

Basis of Presentation

The condensed consolidated financial statements include the accounts of Larimar and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated. The accompanying condensed consolidated financial statements have been prepared in conformity with GAAP. Unless otherwise noted, all references to common stock share and per share amounts have also been adjusted to reflect the Exchange Ratio.

Reverse Stock Split

On May 28, 2020, immediately prior to the closing of the Merger, Zafgen effected the Reverse Stock Split. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split. Unless otherwise noted, all references to common stock share and per share amounts have also been adjusted to reflect the Exchange Ratio.

Going Concern Assessment

In accordance with Accounting Standards Update (“ASU”) No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

As of the issuance date of these condensed consolidated financial statements, the Company expects that its cash, cash equivalents and marketable debt securities will be sufficient to fund its forecasted operating expenses and capital expenditure requirements for at least the next twelve months from the issuance date of these financial statements.

The Company has funded its operations to date primarily with proceeds from sales of common stock, prefunded warrants for the purchase of common stock and, prior to the merger with Zafgen described above, contributions from Holdings. In June 2020, the Company completed the Merger and acquired \$42.9 million of cash, cash equivalents, restricted cash and marketable debt securities that were held by Zafgen immediately prior to the Merger. The Company also raised \$75.4 million, net of offering costs, through a private offering of common stock and prefunded warrants to purchase shares of common stock in connection with and immediately after the closing of the Merger in June 2020.

In August 2020, the Company entered into an Equity Distribution Agreement (the “ATM Agreement”) with an investment bank in connection with the establishment of an “at-the-market” offering program under which the Company may sell up to an aggregate of \$50,000,000 of shares of its common stock from time to time through this investment bank as sales agent. In July 2021, the Company sold 2,342,720 shares pursuant to the ATM Agreement for gross proceeds of \$20.5 million. As of August 10, 2021, the Company may sell up to \$29.2 million of common stock under the ATM Agreement.

Since its inception, the Company has incurred significant operating losses and negative cash flows from operations. The Company has incurred recurring losses since inception, including net losses of \$24.7 million and \$18.0 million for six months ended June 30, 2021 and 2020, respectively. In addition, as of June 30, 2021, the Company had an accumulated deficit of \$90.3 million. The Company expects to continue to generate operating losses for the foreseeable future. As of June 30, 2021, the Company had approximately \$70.6 million of cash and cash equivalents available for use to fund its operations.

The Company has not yet commercialized any products and does not expect to generate revenue from the commercial sale of any products for several years, if at all. The Company expects that its research and development and general and administrative expenses will continue to increase and, as a result, will need additional capital to fund its future operations, which it may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances and licensing arrangements.

If the Company is unable to obtain future funding when needed, the Company may be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or pre-commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. There is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The condensed consolidated balance sheet as of December 31, 2020 was derived from the Company’s audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of June 30, 2021 and for the three and six months ended June 30, 2021 and 2020, have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”), for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the notes thereto for the year ended December 31, 2020 included in the Company’s Annual Report on Form 10-K filed on March 4, 2021.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of June 30, 2021 and condensed consolidated results of operations and cash flows for the three and six months ended June 30, 2021 and 2020 have been made. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expense, valuation of stock-based awards and valuation of leases. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company generally maintains cash balances in various operating accounts at financial institutions that management believes to be of high credit quality in amounts that may exceed federally insured limits. The Company has not experienced losses related to its cash and cash equivalents.

The Company is highly dependent on third-party manufacturers to supply products for research and development activities in its programs. The Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for drug substance and formulated drugs related to these programs. The drug substance which is in frozen liquid form for CTI-1601 is currently manufactured for us by a third-party manufacturer, and the frozen liquid form of drug product is made at another manufacturer. The Company is undertaking a program with a third manufacturer to begin to produce a lyophilized version of the drug product from the same drug substance, that, once available, we intend to use in certain of our future planned clinical trials. The Company's research and development programs could be adversely affected by a significant interruption in these manufacturing services or in the supply of drug substance and formulated drugs.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. At June 30, 2021 and December 31, 2020, cash equivalents consisted of commercial paper and corporate bonds with maturity dates of less than three months at the date of acquisition and money market funds.

Marketable debt securities

Marketable debt securities consist of debt investments with original maturities greater than ninety days. The Company classifies its marketable debt securities as available-for-sale. Accordingly, these investments are recorded at fair value, which is based on quoted market prices. When the fair value is below the amortized cost, the amount of the expected credit loss is estimated. The credit-related impairment amount is recognized in net income; the remaining impairment amount and unrealized gains are reported as a component of accumulated other comprehensive income in stockholders' equity. Credit losses are recognized through the use of an allowance for credit losses account and subsequent improvements in expected credit losses are recognized as a reversal of the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, the allowance for credit loss is written off and the excess of the amortized cost basis of the asset over its fair value is recorded in net income.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over a five or seven-year estimated useful life for equipment, furniture and fixtures and office equipment. Leasehold improvements are amortized over the shorter of the asset life or the term of the lease agreement. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment, net, and the net operating lease asset. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. Any impairment loss, if indicated, is measured as the amount by which the carrying amount of the asset exceeds the estimated fair value of the asset.

Segment Information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's focus is on the research, development, and commercialization of novel therapeutics for the treatment of rare diseases.

Research and Development Costs

Costs associated with internal research and development and external research and development services, including drug development and non-clinical studies, are expensed as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation, stock-based compensation, third-party license fees, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, non-clinical and clinical development activities, and clinical trials as well as to manufacture clinical trial materials, and other costs. The Company recognizes external research and development costs based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments, milestone payments and annual maintenance fees under license agreements are currently expensed in the period in which they are incurred.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-Based Compensation

The Company measures all stock-based awards granted to employees, non-employee consultants and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. Compensation expense of those awards is recognized over the requisite service period, which is the vesting period of the respective award. Typically, the Company issues awards with only service-based and market-based vesting conditions and records the expense for these awards using the straight-line method. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Prior to May 28, 2020, the Company had been a private company and lacked company-specific historical and implied volatility information for its common stock. Therefore, the Company estimates its expected common stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield considers the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the condensed consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Basic shares outstanding includes the weighted average effect of the Company's prefunded warrants issued in June 2020, the exercise of which requires little or no consideration for the delivery of shares of common stock. Basic and diluted weighted average shares of common stock outstanding for the three and six months ended June 30, 2021 and 2020 includes the weighted average effect of 628,403 prefunded warrants for the purchase of shares of common stock, which were issued in June 2020, and for which the remaining unfunded exercise price is \$0.01 per share.

Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common shares, as determined using the treasury stock method. For periods in which the Company has reported net losses, diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is antidilutive.

The Company excluded 2,546,962 and 727,024 common stock equivalents, outstanding as of June 30, 2021 and 2020, respectively, from the computation of diluted net loss per share for the three and six months ended June 30, 2021 and 2020 because they had an anti-dilutive impact due to the net loss incurred for the periods.

Prior to the Merger the Company did not have options to purchase common stock or unvested restricted common stock to exclude from the calculation of earnings per share as all outstanding options were for common units of Holdings that upon the Merger converted into options exercisable for the shares of common stock of the Company.

Recently Issued and Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The FASB subsequently issued amendments to ASU 2016-13. This standard requires entities to estimate an expected lifetime credit loss on financial assets ranging from short-term trade accounts receivable to long-term financings and report credit losses using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. The Company adopted the standard on January 1, 2020. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on the Company’s disclosures.

3. Merger Accounting

On May 28, 2020, the Company completed its merger with Zafgen. Based on the Exchange Ratio, immediately following the Merger, former Zafgen stockholders, Zafgen option holders and other persons holding securities or other rights directly or indirectly convertible, exercisable or exchangeable for Zafgen Common Stock (collectively, the “Zafgen Securityholders”) owned approximately 34% of the outstanding capital stock of the combined company, and Holdings, the former Chondrial stockholder, owned approximately 66% of the outstanding capital stock of the combined company. At the closing of the Merger, all shares of Chondrial Common Stock were exchanged for an aggregate of 6,091,250 shares of Zafgen Common Stock, after giving effect to the Reverse Stock Split.

In addition, pursuant to the terms of the Merger Agreement, the Company assumed all outstanding stock options to purchase shares of Zafgen common stock at the closing of the Merger. At the closing of the Merger, such stock options became options to purchase an aggregate of 328,770 shares of the Company’s common stock after giving effect to the Reverse Stock Split.

The total purchase price paid in the Merger has been allocated to the tangible and intangible assets acquired and liabilities assumed of Zafgen based on their fair values as of the completion of the Merger. Transaction costs primarily included bank fees and professional fees associated with legal counsel, auditors, and printers. The following summarizes the purchase price paid in the Merger (in thousands, except share and per share amounts):

Number of shares of the combined organization owned by Zafgen stockholders ⁽¹⁾		3,124,337
Multiplied by the fair value per share of Zafgen common stock ⁽²⁾	\$	11.88
Fair value of consideration issued in effect of the Merger	\$	37,119
Transaction costs	\$	1,715
Purchase price:	\$	<u>38,834</u>

- (1) The number of shares of 3,124,337 represents the historical 37,492,044 shares of Zafgen common stock outstanding immediately prior to the closing of the Merger, adjusted for the Reverse Stock Split.
- (2) Based on the last reported sale price of Zafgen common stock on the Nasdaq Global Market on May 28, 2020, the closing date of the Merger, and after giving effect to the Reverse Stock Split.

The allocation of the purchase price for the Merger was based on estimates of the fair value of the net assets acquired, which was then adjusted for the difference between the purchase price and the fair value of the assets acquired. The following summarizes the allocation of the purchase price to the net tangible and intangible assets acquired (in thousands):

Cash and cash equivalents	\$	40,595
Marketable debt securities		1,014
Other current and noncurrent assets		357
Property and equipment, net		398
Restricted cash		1,339
Right-of-use asset		3,806
Current liabilities		(2,685)
Lease liability, net of current portion		(5,990)
Purchase price	\$	<u>38,834</u>

4. Fair Value Measurements and Marketable Debt Securities

Fair Value Measurements

The Company's assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2021 and December 31, 2020 are measured in accordance with the standards of ASC 820, *Fair Value Measurements and Disclosures*, which establishes a three-level valuation hierarchy for measuring fair value and expands financial statement disclosures about fair value measurements. The valuation hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:

- Level – 1 Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level – 2 Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.
- Level – 3 Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The Company's financial instruments consist primarily of cash, cash equivalents, marketable debt securities, accounts payable and accrued liabilities. For accounts payable and accrued liabilities, the carrying amounts of these financial instruments as of June 30, 2021 and December 31, 2020 were considered representative of their fair values due to their short term to maturity.

The following tables summarize the Company's cash equivalents and marketable debt securities as of June 30, 2021 and December 31, 2020:

	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
(in thousands)				
June 30, 2021				
Cash equivalents:				
Money market funds	\$ 12,978	\$ 12,978	\$ —	\$ —
Commercial paper	5,250	—	5,250	—
Corporate bonds	1,921	—	1,921	—
Total cash equivalents	20,149	12,978	7,171	—
December 31, 2020				
Cash equivalents:				
Money market funds	\$ 4,229	\$ 4,229	\$ —	\$ —
Commercial paper	6,499	—	6,499	—
Corporate bonds	1,907	—	1,907	—
Total cash equivalents	12,635	4,229	8,406	—
Marketable debt securities:				
U.S. Government securities	2,005	—	2,005	—
Commercial paper	22,485	—	22,485	—
Total marketable debt securities	24,490	—	24,490	—
Total cash equivalents and marketable debt securities	\$ 37,125	\$ 4,229	\$ 32,896	\$ —

Marketable Debt Securities

The following tables summarize the Company's marketable debt securities as of December 31, 2020. The Company held no marketable debt securities as of June 30, 2021.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
(in thousands)				
December 31, 2020				
Assets:				
U.S. Government securities	\$ 2,005	\$ —	\$ —	\$ 2,005
Commercial paper	22,484	2	(1)	22,485
	<u>\$ 24,489</u>	<u>\$ 2</u>	<u>\$ (1)</u>	<u>\$ 24,490</u>

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2021	December 31, 2020
(in thousands)		
Prepaid research and development expenses	\$ 2,945	\$ 4,460
Prepaid insurance	201	571
Payroll tax receivable	67	32
Other prepaid expenses and other assets	193	251
	<u>\$ 3,406</u>	<u>\$ 5,314</u>

6. Fixed Assets

Fixed assets, net consisted of the following:

	Useful Life	June 30, 2021	December 31, 2020
(in thousands)			
Computer equipment	5 years	\$ 66	\$ 66
Lab equipment	5 years	1,144	849
Furniture and fixtures	7 years	455	460
Leasehold Improvements	lease term	31	—
		<u>1,696</u>	<u>1,375</u>
Less: Accumulated depreciation		(485)	(335)
		<u>\$ 1,211</u>	<u>\$ 1,040</u>

Depreciation expense during the six months ended June 30, 2021 and 2020 was \$0.2 million and less than \$0.1 million, respectively.

7. Accrued Expenses

	June 30, 2021	(in thousands)	December 31, 2020
Accrued research and development expenses	\$ 4,183		\$ 3,409
Accrued payroll and related expenses	852		1,350
Accrued professional fees	497		924
Accrued other	143		160
	<u>\$ 5,675</u>		<u>\$ 5,843</u>

8. Stockholders' Equity and Stock Options

Common Stock and Prefunded warrants

As of June 30, 2021, the Company's Certificate of Incorporation, as amended and restated, authorized the Company to issue 115,000,000 of \$0.001 par value common stock and 5,000,000 of \$0.001 par value preferred stock. The voting, dividend, and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers, and preferences of the holders of the preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors of the Company (the "Board"), if any. No cash dividends have been declared or paid to date.

On May 28, 2020, the Company entered into a securities purchase agreement with certain accredited investors (the "Purchasers") for the sale by the Company in a private placement of 6,105,359 shares of the Company's common stock and prefunded warrants to purchase an aggregate of 628,403 shares of the Company's common stock, for a price of \$11.88 per share of the common stock and \$11.87 per prefunded warrant. The prefunded warrants are exercisable at an exercise price of \$0.01 and will be exercisable indefinitely. The Purchasers may exercise the prefunded warrants on a cashless basis in the event that there is no effective registration statement covering the resale of the shares of common stock underlying the prefunded warrants on the date in which the Company is required to deliver the shares. The private placement closed on June 1, 2020. The aggregate gross proceeds for the issuance and sale of the common stock and prefunded warrants were \$80.0 million; transaction costs totaled \$4.6 million and resulted in net proceeds of \$75.4 million. The Company's Registration Statement on Form S-3, filed with the SEC on June 26, 2020, registered the resale of 6,105,359 shares of common stock sold and the 628,403 shares of common stock underlying the prefunded warrants. MTS Health Partners served as placement agent to the Company in connection with the private placement. As partial compensation for these services, we issued MTS Health Partners 35,260 shares of common stock.

Equity Distribution Agreement

On August 14, 2020, the Company entered into the ATM Agreement with an investment bank in connection with the establishment of an "at-the-market" offering program under which the Company may sell up to an aggregate of \$50,000,000 of shares of common stock (the "ATM Shares") from time to time (the "Offering").

Under the ATM Agreement, the Company will set the parameters for the sale of ATM Shares, including the number of ATM Shares to be issued, the time period during which sales are requested to be made, limitations on the number of ATM Shares that may be sold in any one trading day and any minimum price below which sales may not be made. Sales of the ATM Shares, if any, under the ATM Agreement may be made in transactions that are deemed to be "at-the-market offerings" as defined in Rule 415 under the Securities Act. The Company will pay its investment bank a commission equal to 3.0% of the gross proceeds of any ATM Shares sold through its investment bank under the ATM Agreement and will reimburse the investment bank for certain specified expenses. The ATM Agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and its investment bank, other customary obligations of the parties and termination provisions. The Company has no obligation to sell any of the ATM Shares and may at any time suspend offers under the ATM Agreement. As of June 30, 2021, 11,524 shares of Common Stock have been sold under the ATM Agreement for net proceeds of \$0.2 million at an average gross price per share of \$21.89.

In July 2021, the Company sold an additional 2,342,720 shares under the ATM Agreement for net proceeds of \$19.9 million. As of August 10, 2021, the Company could sell up to \$29.2 million under the ATM Agreement.

Summary of Plans

Upon completion of the Merger with Zafgen, Zafgen's 2014 Stock Option and Incentive Plan (the "2014 Plan") and Zafgen's 2006 Stock Option Plan (the "2006 Plan" and together with the 2014 Plan the "Prior Plans") were assumed by the Company. As described below, the Company adopted a new equity incentive plan in July 2020 that was approved by the stockholders in September 2020. These three plans are administered by the Board or, at the discretion of the Board, by a committee of the Board.

2020 Equity Incentive Plan

The Company's Board of Directors adopted the 2020 Equity Incentive Plan (the 2020 Plan) on July 16, 2020 and the stockholders of the Company approved the 2020 Plan on September 29, 2020. The 2020 Plan replaces the 2014 Plan. Option outstanding under the Prior Plans will remain outstanding, unchanged, and subject to the terms of the 2014 Plan and the respective award agreements, and no further awards will be made under the 2014 Plan. However, if any award previously granted under the Prior Plans, expires, terminates, is canceled, or is forfeited for any reason after the approval of the 2020 Plan, the shares subject to that award will be added to the 2020 Plan share pool so that they can be utilized for new grants under the 2020 Plan.

The 2020 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, and cash or other stock-based awards. ISOs may be granted only to the Company's employees, including the Company's officers, and the employees of the Company's affiliates. All other awards may be granted to the Company's employees, including the Company's officers, the Company's non-employee directors and consultants, and the employees and consultants of the Company's affiliates.

As of June 30, 2021, 970,349 shares of common stock were available for grant under the 2020 Plan. The maximum number of shares that may be issued in respect of any awards under the 2020 Plan is the sum of: (i) 1,700,000 shares plus (ii) an annual increase on January 1, 2021 and each anniversary of such date thereafter through January 1, 2030, equal to the lesser of (A) 4% of the shares issued and outstanding on the last day of the immediately preceding fiscal year, and (B) such smaller number of shares as determined by the Board (collectively, the "Plan Limit"). As permitted by the plan, the Company added 614,709 shares available for grant to the 2020 Plan on January 1, 2021 increasing the maximum number of shares of the Company's common stock that may be issued under the 2020 plan to 2,314,709 shares. The maximum aggregate number of shares that may be issued under the 2020 Plan in respect of incentive stock options is 8,000,000 over the ten-year term of the 2020 Plan. On May 28, 2021, options to purchase 38,090 shares issued under the 2014 Plan were cancelled and became available under the 2020 Plan.

2014 Stock Option and Incentive Plan and 2006 Stock Option Plan

In 2014, the Board and stockholders of Zafgen adopted the 2014 Plan. The 2014 Plan provided for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance-share awards, cash-based awards and dividend equivalent rights to employees, members of the Board and consultants of the Company. The number of shares initially reserved for issuance under the 2014 Plan was 180,685 shares of common stock. As the 2020 Plan was adopted by the Company and approved by the Company's stockholders, no further awards will be made under the Prior Plans.

2016 Equity and Incentive Plan

Under the 2016 Equity Plan adopted by Holdings on November 30, 2016, (the "2016 Equity Incentive Plan"), the Board of Managers of Holdings (the "Board of Managers") or a committee thereof was authorized to issue 122,133 Common Units of Holdings or combination of Common Units, Common Unit options or profit interest units. On March 23, 2018, the Board of Managers increased the number of Common Units reserved for grant and issuance pursuant to the 2016 Plan from 122,133 to 138,133 and on April 29, 2019 increased the number of Common Units reserved for grant and issuance pursuant to the 2016 Plan by an additional 101,500 to 239,633. The Company has recorded costs incurred as stock-based compensation with a corresponding capital contribution from Holdings.

From January 1, 2020 through the Merger date Holdings did not issue options to purchase Common Units to employees of the Company.

The Company assumed all of the outstanding and unexercised options to purchase units of Holdings upon consummation of the Merger. Pursuant to the terms of the Merger Agreement, options to purchase 330,818 shares of the Company's common stock at a weighted average exercise price of \$12.14 per share were substituted for the 202,392 options to purchase Common Units, with a weighted average exercise price of \$10.36 per Common Unit, that were outstanding immediately prior to the Merger.

The Company treated the conversion as a modification pursuant to ASC 718, *Compensation—Stock Compensation*, and calculated the pre- and post-modification value of the options. The increase in fair value of the options was calculated to be \$1.2 million. As \$0.7 million related to vested options the expense was recognized immediately on the Merger date, the remaining \$0.5 million is recognized over the remaining vesting term with the original grant date fair value remaining of \$0.1 million.

Stock Valuation

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted to employees:

	June 30, 2021	December 31, 2020
Risk-free interest rate	0.88%	0.37%
Expected term (in years)	6.19	6.08
Expected volatility	91%	91%
Dividend yield	0.00%	0.00%

Stock Options

The following table summarizes the Company's stock option activity for the six months ended June 30, 2021 (amounts in millions, except for share and per share data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (a) (in millions)
Outstanding as of December 31, 2020	2,008,902	\$ 22.31	7.9	
Granted	603,050	15.74		
Forfeited/Expired	(64,990)	73.19		
Outstanding as of June 30, 2021	<u>2,546,962</u>	\$ 19.46	8.1	\$ —
Exercisable as of June 30, 2021	<u>597,801</u>	\$ 39.35	4.3	\$ —
Vested and expected to vest as of June 30, 2021	<u>2,546,962</u>	\$ 19.46	8.1	\$ —

- (a) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were in the money at June 30, 2021.

2021 Option Grants

During the six months ended June 30, 2021, the Company granted options to purchase 603,050 shares of common stock to employees and directors of the Company under the 2020 Plan. The options have an exercise price equal to the closing stock price as of the grant date. Of the 603,050 options granted in 2021, 553,250 vest over four years, with 25% vesting on the first anniversary of the grant and the remainder vesting in equal monthly installments thereafter, the remaining 49,800 options were annual grants to directors and vest one year from the grant date.

Stock-Based Compensation

Stock-based compensation expense was classified in the condensed consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands)			
Research and development	\$ 515	\$ 199	\$ 953	\$ 211
General and administrative	835	553	1,577	570
	<u>\$ 1,350</u>	<u>\$ 752</u>	<u>\$ 2,530</u>	<u>\$ 781</u>

As of June 30, 2021, total unrecognized compensation expense related to unvested stock options and restricted stock units was \$17.7 million, which is expected to be recognized over a weighted average period of 3.12 years.

9. Commitments

Intellectual Property Licenses

The Company is party to an exclusive License Agreement (the “WFUHS License”), dated November 30, 2016 with Wake Forest University Health Sciences (“WFUHS”) and an exclusive License Agreement (the “IU License”), dated November 30, 2016, as amended, with Indiana University (“IU”). Such agreements provide for a transferable, worldwide license to certain patent rights regarding technology used by the Company with respect to the development of CTI-1601.

In partial consideration for the right and license granted under these agreements, the Company will pay each of WFUHS and IU a royalty of a low single digit percentage of net sales of licensed products depending on whether there is a valid patent covering such products. As additional consideration for these agreements, the Company is obligated to pay each of WFUHS and IU certain milestone payments of up to \$2.6 million in the aggregate upon the achievement of certain developmental milestones, commencing on the enrollment of the first patient in a Phase 1 clinical trial. The Company will also pay each of WFUHS and IU sublicensing fees ranging from a high-single digit to a low double-digit percentage of sublicense consideration depending on the Company’s achievement of certain regulatory milestones as of the time of receipt of the sublicense consideration. The Company is also obligated to reimburse WFUHS and IU for patent-related expenses. In the event that the Company disputes the validity of any of the licensed patents, the royalty rate would be tripled during such dispute. The Company is also obligated to pay to IU a minimum annual royalty of less than \$0.1 million per annum starting in the 2020 calendar year for the term of the agreement.

In the event that the Company is required to pay IU consideration, then the Company may deduct 20% of such IU consideration on a dollar-for-dollar basis from the consideration due to WFUHS. In the event that the Company is required to pay WFUHS consideration, then the Company may deduct 60% of such WFUHS consideration on a dollar-for-dollar basis from the consideration due to IU.

During the three and six months ended June 30, 2021, no milestones were achieved and no expense was recognized. Both agreements continue from their effective date through the last to expire of the licensed patents unless earlier terminated by either party.

Leases

On August 8, 2019, the Company entered into an operating lease for office space in Bala Cynwyd, Pennsylvania, effective as of December 15, 2019, for a period of three years and six months with an option to extend the lease for three additional years. Due to required tenant improvements to be completed by the landlord, the Company did not take immediate possession of the leased property and the lease term commenced on February 15, 2020. In the quarter ended March 31, 2020, the Company recorded an operating lease right-of-use asset and operating lease liability of \$0.4 million.

On May 28, 2020, as part of the Merger with Zafgen, the Company acquired a non-cancellable operating lease for approximately 17,705 square feet of office space (the “Premises”). The lease expires on October 30, 2029. As part of the agreement, the Company is required to maintain a letter of credit, which upon signing was \$1.3 million and is classified as restricted cash within the condensed consolidated financial statements. In addition to the base rent, the Company is also responsible for its share of operating expenses, electricity and real estate taxes, which costs are not included in the determination of the leases’ right-of-use assets or lease liabilities. The right-of-use asset is being amortized to rent expense over the remaining lease term.

On October 27, 2020, the Company entered into a sublease agreement (the “Sublease”) with Massachusetts Municipal Association, Inc. (the “Subtenant”), whereby the Company subleased the entire Premises to the Subtenant. The initial term of the Sublease commenced on December 4, 2020 and continues until October 30, 2029. In connection with the Sublease, the Company evaluated the need for impairment under ASC 360 and determined there was no impairment.

The Sublease provides for an initial annual base rent of \$0.8 million, which increases annually up to a maximum annual base rent of \$1.0 million. The Subtenant also is responsible for paying to the Company future increases in operating costs (commencing on January 1, 2022), future increases in annual tax costs (commencing July 1, 2021) and all utility costs (commencing March 1, 2021) attributable to the Premises during the term of the Sublease. As part of the Sublease, the subtenant deposited a letter of credit in the amount of \$0.8 million to assure their performance under the sublease. If there are no uncured events of default under the sublease, the amount of this security deposit decreases over time to \$0.4 million on the sixth anniversary of the Sublease.

On November 5, 2018, the Company entered into an operating lease for office and lab space in Philadelphia, Pennsylvania, effective as of January 1, 2019, and expiring on December 31, 2020 with an option to extend the lease for two additional years. On August 4, 2020, the Company executed the first option to extend the lease for an additional year, expiring on December 31, 2021. We have determined this lease extension qualifies as a short-term lease, as the remaining renewal option is not considered reasonably certain, for which we have applied the accounting policy election to not record the related right-of-use asset and lease liabilities.

Expense arising from operating leases was \$0.1 million during the three and six months ended June 30, 2021, and \$0.1 million during the three and six months ended June 30, 2020. For operating leases, the weighted-average remaining lease term for leases at June 30, 2021 and December 31, 2020 was 8.1 and 8.6 years, respectively. For operating leases, the weighted average discount rate for leases at June 30, 2021 and December 31, 2020 was 11.0%. The Company has not entered into any financing leases.

Maturities of lease liabilities due under these lease agreements as of June 30, 2021 are as follows:

(in thousands)	Operating Leases
Six months ending December 31, 2021	\$ 590
Year ended December 31, 2022	1,197
Year ended December 31, 2023	1,146
Year ended December 31, 2024	1,065
Year ended December 31, 2025	1,083
Thereafter	4,314
Total lease payments	9,395
Less: imputed interest	(3,127)
Present value of lease liabilities	\$ 6,268

10. Related Party Transactions

In November 2016, the Company entered into a consulting agreement with Mark Payne, M.D (the “Consulting Engagement”). Dr. Payne was a director of Chondrial at that time, a full-time employee of IU and one of the inventors of the licensed IU intellectual property, and as such is entitled to a certain share of the revenues received by IU under the IU License. Pursuant to the terms of his consulting agreement the Company agreed to pay Dr. Payne \$0.1 million per year over the term of the agreement and granted Dr. Payne 123,853 restricted Common Units in Holdings. On November 30, 2016, 30% immediately vested and was associated with Chondrial Therapeutics IP, LLC (“IP LLC”) becoming a subsidiary of Holdings, which subsequently contributed to the Company on December 31, 2018. The remaining 70% vested ratably over 48 months beginning on December 1, 2016 and were fully vested as of December 31, 2020. The consulting agreement has a four-year term, subject to earlier termination. On November 30, 2020, The Company entered into a 1-month extension of the Consulting Engagement, expiring on December 31, 2020 and on January 1, 2021, the Company entered into a new consulting agreement with Mark Payne, M.D. which extended the term of the Consulting Engagement for a four-year term beginning on January 1, 2021. During the three and six months ended June 30, 2021 and 2020 the Company recognized less than \$0.1 million and \$0.1 million, respectively, related to this consulting agreement, recorded as research and development expense in the Statement of Operations.

The funding to the Company originated from Holdings’ sale of Series A Preferred Units and Series B convertible preferred units (the “Units”) with Deerfield Private Design Fund IV, L.P., Deerfield Private Design Fund III, L.P. and Deerfield Health Innovations Fund, L.P. (together, the “Deerfield Funds”), and certain other purchasers, from inception through May 28, 2020 and the contribution of the proceeds received by Holdings on such sales to the Company in order to fund the Company’s operations

Under a November 30, 2016 Series A Preferred Unit Purchase Agreement, as amended on September 8, 2017, November 15, 2017, November 14, 2018 and April 29, 2019, Holdings sold Series A Preferred Units for gross proceeds of \$35.6 million. The gross proceeds of \$35.6 million were contributed to the Company.

On November 21, 2019 (as amended on December 20, 2019), Holdings entered into a Second Amended and Restated LLC Agreement and entered into a Series B Bridge Unit Purchase Agreement with the Deerfield Funds and certain other purchasers to sell Series B convertible preferred units (“Series B Bridge Units”) for gross proceeds of up to \$10.0 million. The gross proceeds of \$10.0 million were contributed to the Company.

On January 16, 2020, Holdings entered into a Third Amended and Restated LLC Agreement and entered into a Second Series B Bridge Unit Purchase Agreement with the Deerfield Funds and certain other purchasers to sell Second Series B convertible preferred units (“Second Series B Bridge Units”) for gross proceeds of up to \$15.0 million. The gross proceeds of \$11.4 million were contributed to the Company.

During the six months ended June 30, 2020, Holdings provided the Company non-interest bearing, permanent funding from the above Series A and Series B preferred unit transactions, totaling \$18.0 million, which were recorded as capital contributions with the balance of combined equity and additional paid in capital on the condensed consolidated balance sheets and condensed consolidated statements of changes in stockholders’ equity for each respective period.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, (“Quarterly Report”), and the audited consolidated financial statements and notes thereto and management’s discussion and analysis of financial condition and results of operations for the year ended December 31, 2020 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”), on March 4, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties, and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. You should read the “Risk Factors” section included in our Annual Report on Form 10-K filed with the SEC on March 4, 2021, and the “Risk Factors” and “Forward-Looking Statements” sections of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company focused on developing treatments for patients suffering from complex rare diseases using our novel cell penetrating peptide technology platform. Our lead product candidate, CTI-1601, is a subcutaneously administered, recombinant fusion protein intended to deliver human frataxin (“FXN”), an essential protein, to the mitochondria of patients with Friedreich’s ataxia (FA). Friedreich’s ataxia is a rare, progressive, and fatal disease in which patients are unable to produce enough FXN due to a genetic abnormality. There is currently no effective therapy for Friedreich’s ataxia.

We have received orphan drug designation, fast track designation and rare pediatric disease designation, from the U.S. Food and Drug Administration (the FDA), for CTI-1601. In addition, we received orphan drug designation for CTI-1601 from the European Commission and Priority Medicines (PRIME) designation from the European Medicines Agency (EMA). The receipt of such designations or positive opinions may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA or EMA procedures and does not assure ultimate approval by the FDA or EMA.

Our cell penetrating peptide technology platform, which enables a therapeutic molecule to cross a cell membrane in order to reach intracellular targets, has the potential to enable the treatment of other rare and orphan diseases. We intend to use our proprietary platform to target additional orphan indications characterized by deficiencies in or alterations of intracellular content or activity.

CTI-1601 Program Update

On May 20, 2021 we announced that we had received EMA PRIME designation for CTI-1601 in FA. Through PRIME, the EMA offers early and proactive support to medicine developers to optimize the generation of robust data on a medicine’s benefits and risks and enable accelerated assessment of medicines applications so that these medicines can reach patients earlier. The PRIME designation was based on both pre-clinical data as well as tolerability data from the CTI-1601 Phase 1 program in patients with FA.

In May 2021, we reported positive topline data from our Phase 1 Friedreich’s ataxia (FA) program after completing dosing of the single ascending dose (SAD) trial in December 2020 and of the multiple ascending dose (MAD) trial in March 2021. Data from these trials demonstrate proof-of-concept by showing that daily subcutaneous injections of CTI-1601 for up to 13 days resulted in dose-dependent increases in frataxin levels from baseline compared to placebo in all evaluated tissues (buccal cells, skin, and platelets). Frataxin levels achieved in peripheral tissues (buccal cells) following daily 50 mg and 100 mg subcutaneous injections of CTI-1601 were at or in excess of frataxin levels that would be expected in phenotypically normal heterozygous carriers. There were no serious adverse events (SAEs), associated with either the MAD or SAD trials.

On May 25, 2021 the FDA placed a clinical hold on the CTI-1601 clinical program following our notification to the FDA of mortalities which occurred at the highest dose levels the then ongoing 180-day non-human primate (NHP) toxicology study, which is 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 ongoing NHP study and that we may not initiate additional clinical trials until we have submitted the report and received notification from the FDA that additional clinical trials may commence. At the time of this notice, we had no interventional clinical trials with patients enrolled or enrolling.

In July 2021, we completed dosing in the NHP toxicology study discussed above. We are currently collecting and analyzing data from the study. While there is no way to predict the FDA's response or whether they will require additional data or testing, we expect to initiate our Jive open-label extension and pediatric MAD trials in the first half of next year, subject to the FDA lifting the clinical hold on CTI-1601, in full or in part.

Financial Overview and Liquidity

Since our inception, we have devoted substantially all of our resources to developing CTI-1601, building our intellectual property portfolio, developing third-party manufacturing capabilities, business planning, raising capital, and providing general and administrative support for such operations.

We have never generated any revenue and have, to date, incurred net losses. We incurred net losses of approximately \$24.7 million and \$18.0 million for six months ended June 30, 2021, and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$90.3 million. Our losses have resulted principally from costs incurred in connection with research and development activities, and general and administrative costs associated with our operations. We expect to incur significant expenses and operating losses for the foreseeable future.

We expect to continue to incur expenses in connection with our ongoing activities, if and as we:

- Continue to advance the development of CTI-1601 through additional clinical trials;
- Seek to identify and advance development of additional product candidates into clinical development and identify additional indications for our product candidates;
- Seek to obtain regulatory approvals for our product candidates;
- Identify, acquire or in-license other product candidates and technologies;
- Maintain, leverage, and expand our intellectual property portfolio; and
- Expand our operational, financial and management systems and personnel, including personnel to support our clinical development and future commercialization efforts and our operations as a public company.

As a result, we will need additional financing to support our continuing operations. Until such time that we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public equity, private equity, debt financings, or other sources, which may include collaborations with third parties. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or product candidates. In addition, we may never successfully complete development of any of our product candidates, obtain adequate patent protection for our technology, obtain necessary regulatory approvals for our product candidates, or achieve commercial viability for any approved product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on its financial condition and ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability and may never do so.

At June 30, 2021, we had cash, cash equivalents and marketable debt securities balance totaling \$70.6 million. In July 2021, we sold 2,342,720 shares of common stock for net proceeds of \$19.9 million (See "Liquidity and Capital Resources"). We believe that, based on our current operating plan, our cash, cash equivalents and marketable debt securities as of the filing date of this Quarterly Report on Form 10-Q will enable us to fund operations for at least twelve months from the issuance of our interim financial statements for the quarterly period ended June 30, 2021.

COVID-19 Update

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of Coronavirus, a global pandemic. The pandemic resulted in the temporary stoppage of our CTI-1601 Phase 1 clinical trials in patients with Friedreich's ataxia in March 2020. In July 2020, we resumed these clinical trials, and have since completed dosing of both our SAD and MAD clinical trials. Vaccines manufactured by Moderna, Pfizer and Johnson & Johnson were introduced late in the fourth quarter of 2020 and became widely available by the end of the first quarter of 2021. While the vaccines have proven effective in reducing the severity and mortality of COVID-19 including the variants that have evolved to date, the overall vaccination rate in the United States has not reached the level required for herd immunity in some states, particularly in some areas of the country. The incidence of variants of COVID-19, has been increasing particularly among unvaccinated individuals and the variants are proving to be more easily spread than earlier variants. The low vaccination rate, the spread of the variants, the evolution of furthermore deadly mutations against which the current vaccines may prove ineffective could again result in major disruptions to businesses and markets worldwide. The Company's business, results of operations, financial condition and cash flows could be materially and adversely affected. Specifically, we could experience additional delays in future clinical trial timelines as a result of additional travel and hospital restrictions related to the COVID-19 pandemic which may be imposed, experience supply shortages or manufacturer shutdowns impacting the manufacture of drug substance or drug product. The financial statements do not reflect any adjustments as a result of the pandemic.

Merger with Zafgen

On December 17, 2019, we entered into an Agreement and Plan of Merger, (the "Merger Agreement") with Zordich Merger Sub, Inc. ("Merger Sub"), our wholly owned subsidiary, Chondrial Therapeutics Inc. ("Chondrial"), and Chondrial Holding, LLC ("Holdings") pursuant to which the Merger Sub would merge with and into Chondrial, with Chondrial surviving the merger as our wholly owned subsidiary (the "Merger"). The Merger was completed on May 28, 2020 pursuant to the terms of the Merger Agreement.

Pursuant to the terms of the Merger Agreement, upon closing of the Merger, all of Chondrial's outstanding common stock was exchanged for our common stock and all outstanding options exercisable for units of Holdings were exchanged for options to purchase our common stock. In addition, immediately prior to the closing of the Merger, we effected a 1 for 12 reverse stock split and changed our name from Zafgen, Inc. to Larimar Therapeutics, Inc. Following the Merger, the business conducted by Chondrial became our primary business.

The business combination was accounted for as a reverse acquisition in accordance with U.S. generally accepted accounting principles ("GAAP"). Under this method of accounting, Chondrial was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the facts that, immediately following the merger: (i) former Chondrial stockholders owned a substantial majority of the voting rights in the combined company, (ii) the majority of the board of directors of the combined company was composed of directors designated by Chondrial under the terms of the Merger Agreement and (iii) existing members of Chondrial management became the management of the combined company. Accordingly, for accounting purposes, the business combination was treated as the equivalent of Chondrial issuing stock to acquire Zafgen's net assets. As a result, as of the closing date of the Merger, Zafgen's net assets were recorded at their acquisition-date fair values, which were then adjusted for the difference between the purchase price and the fair value of the assets acquired, in the financial statements of Chondrial and the reported operating results prior to the business combination are those of Chondrial. As the Merger has been accounted for as an asset acquisition, goodwill has not been recorded within the condensed combined balance sheet.

Private Placement

On May 28, 2020, we entered into a Securities Purchase Agreement with certain accredited investors for the sale by us in a private placement of 6,105,359 shares of our common stock (the "Private Placement Shares"), and pre-funded warrants to purchase an aggregate of 628,403 shares of our common stock (the "Pre-funded Warrants"). The Pre-Funded Warrants are immediately exercisable at an exercise price for \$0.01 and are exercisable indefinitely. We refer to this sale herein as the Private Placement.

The Private Placement closed on June 1, 2020. The aggregate gross proceeds for the issuance and sale of the Private Placement Shares and Pre-Funded common stock Warrants were \$80.0 million and, after deducting certain of our expenses, the net proceeds we received in the Private Placement were \$75.4 million. We intend to use the net proceeds from the Private Placement for research and development of our product candidates, working capital and general corporate purposes.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales, and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates or collaborations.

Operating Expenses

The majority of our operating expenses since inception have consisted primarily of research and development activities, and general and administrative costs.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of:

- third-party contract costs relating to research, formulation, manufacturing, non-clinical studies, and clinical trial activities;
- employee related costs, including salaries, benefits and stock-based compensation expenses for employees engaged in scientific research and development functions;
- external costs of outside consultants and vendors;
- payments made under our third-party licensing agreements;
- sponsored research agreements;
- laboratory consumables; and
- allocated facility-related costs.

Costs for certain activities, such as manufacturing, non-clinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators. Research and development activities are central to our business. We expect to increase our investment in research and development in order to advance CTI-1601 through additional clinical trials. As a result, we expect that our research and development expenses will increase in the foreseeable future as we pursue clinical development of CTI-1601 and/or any other product candidates we develop.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of CTI-1601 or any other product candidates we develop. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. The duration, costs, and timing of clinical trials and development of CTI-1601 or any other product candidates we develop will depend on a variety of factors, including:

- the scope, rate of progress and expense of clinical trials and other research and development activities, including the ongoing impact of COVID-19 on these activities;
- clinical trial results;
- uncertainties in clinical trial enrollment rate or design;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals;
- the influence of the FDA's or other regulatory authority's on our clinical trial design and timing;

- establishing manufacturing capabilities or making arrangements with third-party manufacturers and risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- the impact of the on-going COVID-19 pandemic including the mutations of the original virus that may prove more contagious and deadly;
- our ability to obtain and maintain patent and trade secret protection and regulatory exclusivity for our product candidates; and
- our ability to retain key research and development personnel.

A change in the outcome of any of these variables with respect to the development of a product candidate could significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, consisting of salaries, related benefits and stock-based compensation, costs related to our executive, finance, information technology, and costs related to other administrative functions. General and administrative expenses also include, insurance expenses, and professional fees for auditing, tax, and legal services, including legal expenses to pursue patent protection of our intellectual property. We expect that our general and administrative expenses will increase in the foreseeable future as we hire additional employees to implement, improve and scale our operational, financial and management systems.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, costs and expenses, and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our condensed consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate these estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

Research and Development Expenses

As part of the process of preparing our condensed consolidated financial statements, we are required to estimate our accrued research and development expenses and evaluate payments made to vendors in advance of actual work activities being performed. This process involves reviewing open contracts and purchase orders, communicating with our personnel and outside vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our condensed consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs, in connection with clinical trials;
- vendors in connection with non-clinical development activities;
- contract manufacturing organizations in connection with the production of non-clinical and clinical trial materials; and
- vendors related to product candidate manufacturing, development, and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs or CMOs that conduct and manage clinical trials or manufacture clinical trial material on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense, non-clinical expense, or manufacturing activities. Payments under some of these contracts depend on factors such as the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. In accruing CMO costs, we estimate the time period that manufacturing will be completed, the achievement of milestones and the percentage of completion of each specific CMO agreement. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us recognizing adjustments in future periods as additional information becomes available.

Stock-Based Compensation

We measure all stock-based awards granted to employees, non-employee consultants and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. Compensation expense of those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Typically, we issue awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We account for forfeitures as they occur.

We classify stock-based compensation expense in our condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Prior to May 28, 2020, we were a private company and lacked company-specific historical and implied volatility information for our common stock. Therefore, we estimate our expected common stock price volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options have been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield considers the fact that we have never paid cash dividends on common stock and do not expect to pay any cash dividends in the foreseeable future.

Results of Operations

Comparison of three months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		
	2021	2020	Increase (Decrease)
	(in thousands)		
Statement of Operations Data:			
Operating expenses:			
Research and development	\$ 9,102	\$ 8,907	\$ 195
General and administrative	3,441	2,492	949
Total operating expenses	12,543	11,399	1,144
Loss from operations	(12,543)	(11,399)	(1,144)
Other income (expense), net	(66)	69	(135)
Net loss	\$ (12,609)	\$ (11,330)	\$ (1,279)

Research and development expenses

Research and development expenses for the three months ended June 30, 2021 increased \$0.2 million compared to the three months ended June 30, 2020. The increase in research and development expenses compared to the prior year period was primarily driven by higher non-clinical costs of \$1.5 million associated with ongoing assay and toxicology studies, an increase of \$0.9 million in clinical trial costs related to the start of the Jive study preparation work, an increase of \$0.7 million in personnel related costs due to headcount additions in our research and development functions, 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 \$3.1 million in clinical supply manufacturing costs.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2021 increased \$0.9 million compared to the three months ended June 30, 2020. The increase in general and administrative expenses as compared to the prior year period was primarily driven by an increase of \$0.3 million in personnel related costs due to increased headcount, 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, and an increase of \$0.5 million in professional fees primarily associated with insurance costs, legal and consulting fees as a result of operating as a public company.

Results of Operations

Comparison of six months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,		
	2021	2020	Increase (Decrease)
	(in thousands)		
Statement of Operations Data:			
Operating expenses:			
Research and development	\$ 18,076	\$ 13,914	\$ 4,162
General and administrative	6,573	4,159	2,414
Total operating expenses	<u>24,649</u>	<u>18,073</u>	<u>6,576</u>
Loss from operations	(24,649)	(18,073)	(6,576)
Other income (expense), net	(48)	69	(117)
Net loss	<u>\$ (24,697)</u>	<u>\$ (18,004)</u>	<u>\$ (6,693)</u>

Research and development expenses

Research and development expenses for the six months ended June 30, 2021 increased \$4.2 million compared to the six months ended June 30, 2020. The increase in research and development expenses compared to the prior year period was primarily driven by an increase of \$2.4 million in clinical trial costs related to the completion of the SAD and MAD studies in early 2021 and the start of the Jive study preparation work, higher non-clinical costs of \$1.6 million associated with the ongoing assay and toxicology studies, an increase of \$1.3 million in personnel related costs due to increased headcount in our research and development functions, an increase of \$0.7 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 \$1.9 million in clinical supply manufacturing costs.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2021 increased \$2.4 million compared to the six months ended June 30, 2020. The increase in general and administrative expenses as compared to the prior year period was primarily driven by an increase of \$0.6 million in personnel related costs due to increased headcount, an increase of \$1.0 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 \$1.5 million in professional fees primarily associated with insurance costs, recruiting expenses, legal and consulting fees as a result of operating as a public company, partially offset by a decrease of \$0.7 million in accounting and audit costs related to additional years under audit in the first quarter 2020.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from our operations. We have devoted substantially all of our resources to developing CTI-1601, building our intellectual property portfolio, developing third-party manufacturing capabilities, business planning, capital raising, and providing general and administrative support for such operations.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented below:

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (21,988)	\$ (21,120)
Net cash provided by investing activities	24,470	40,643
Net cash provided by financing activities	—	93,480
Net increase in cash, cash equivalents and restricted cash	<u>\$ 2,482</u>	<u>\$ 113,003</u>

Net cash used in operating activities

During the six months ended June 30, 2021, operating activities used \$22.0 million of cash, resulting from our net loss of \$24.7 million, adjusted for noncash expenses of \$2.7 million. Our net loss was primarily attributable to research and development activities related to our CTI-1601 program and our general and administrative expenses as described above. Noncash expenses primarily include stock-based compensation expense. The change in operating assets and liabilities was primarily due to a decrease in prepaid expenses and accounts payable.

During the six months ended June 30, 2020, operating activities used \$21.1 million of cash, resulting from our net loss of \$18.0 million, adjusted for noncash expenses of \$0.8 million and changes in our operating assets and liabilities of \$4.0 million. Noncash expenses primarily include stock-based compensation expense. The change in operating assets and liabilities was primarily due to an increase in accounts payable, accrued expenses and prepaid expenses due to the growth in our operating activities.

Net cash provided by (used in) investing activities

During the six months ended June 30, 2021, investing activities provided \$24.5 million of cash, resulting from a \$26.3 million increase from maturities of marketable debt securities, which was partially offset by \$1.7 million in purchases of new marketable debt securities.

During the six months ended June 30, 2020, investing activities used \$40.6 million of cash, resulting from a \$41.9 million increase from our Merger, which was offset by transaction costs associated with the Merger of \$1.2 million and \$0.1 million from the purchase of equipment.

Net cash provided by financing activities

During the six months ended June 30, 2021, there was no cash provided by financing activities.

During the six months ended June 30, 2020, net cash provided by financing activities of \$93.5 million was the result of contributions from Holdings.

Operating Capital Requirements

CTI-1601 is currently in clinical development. We recently completed the dosing of two phase 1 clinical trials and expect to initiate additional interventional studies of CTI-1601 in Friedreich ataxia in the first half of 2022, as well as initiate a non-interventional healthy volunteer study beginning in the second half of this year; therefore, we expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that we will continue to incur expenses, if and as we seek to:

- advance the development of CTI-1601 through additional clinical trials, including the cost of clinical materials as well as manufacturing scale up costs;
- identify and advance development of additional product candidates into clinical development and identify additional indications for our product candidates;
- obtain regulatory approvals for our product candidates;
- identify, acquire or in-license other product candidates and technologies;
- maintain, leverage, and expand our intellectual property portfolio; and
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development and future commercialization efforts and our operations as a public company.

We expect to continue to generate operating losses for the foreseeable future. We completed the Merger on May 28, 2020 which, upon closing, provided cash, cash equivalents, restricted cash, and marketable debt securities of \$42.9 million concurrent with the Private Placement which provided additional net proceeds of \$75.4 million. In August 2020, we entered into an Equity Distribution Agreement, or the ATM Agreement, with an investment bank, in connection with the establishment of an “at-the-market” offering program under which we may sell up to an aggregate of \$50,000,000 of shares of our common stock from time to time through this investment bank, as sales agent. As of June 30, 2021, 11,524 shares of common stock have been sold under the Agreement for net proceeds of \$0.2 million at an average gross price per share of \$21.89. During the first half of 2021, no sales of common stock were sold under the ATM Agreement. In July 2021, the Company sold an additional 2,342,720 shares under the ATM Agreement for net proceeds of \$19.9 million.

We believe that, based on our current operating plan, our cash, cash equivalents and marketable debt securities as of the filing date will enable us to fund operations for at least twelve months from the issuance of our interim financial statements for the quarterly period ended June 30, 2021.

Until such time, if ever, as we can generate substantial revenue, we expect to seek additional funding through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances, and licensing arrangements. We may not be able to obtain financing on acceptable terms, or at all, and we may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or our existing stockholders’ rights. If we are unable to obtain additional funding, we will be forced to delay, reduce, or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which would adversely affect our business, or we may be unable to continue operations.

Off-Balance Sheet Arrangements

During the periods presented we did not have, and we currently do not have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Recently Issued Accounting Pronouncements

Please read Note 2 to our condensed consolidated financial statements included in Part I of Item 1 of this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Other Company Information

None.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (Exchange Act) and are not required to provide the information under this item.

Item 4. Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2021, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2021 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to claims in legal proceedings arising in the normal course of business. To our knowledge, there are no threatened or pending legal actions that could reasonably be expected to have a material adverse effect on our business, financial condition, results of operations or cash flows.

Item 1A. Risk Factors

You should carefully consider the risk factors described in our 2020 Annual Report and in our Quarterly Report for the period ended March 31, 2021 under the caption "Item 1A. Risk Factors" Except as set forth below, there have been no material changes in our risk factors disclosed in our 2020 Annual Report and our Quarterly Report for the period ended March 31, 2021.

The FDA has placed a clinical hold on CTI-1601. Our business may be adversely affected if the clinical hold cannot be favorably resolved in a timely manner or if such regulatory concerns lead to more burdensome preclinical or clinical studies that cause significant delays or expense in developing CTI-1601.

On May 25, 2021 the FDA placed a clinical hold on the CTI-1601 investigational new drug application (IND) clinical program following our notification to the FDA of mortalities which occurred at the highest dose levels in an ongoing 180-day non-human primate (NHP) toxicology study, which is designed to support extended dosing of patients with CTI-1601. In the clinical hold letter, the FDA stated it needs a full study report from the ongoing NHP study and we may not initiate additional clinical trials until we have submitted the report and received notification from the FDA that additional clinical trials may commence.

We cannot be certain whether or when the FDA will lift the clinical hold and allow us to pursue further development of CTI-1601 in the United States. If the FDA does not lift the clinical hold in a timely manner, or at all, our development timelines and our business may be adversely affected and our stock price may decline. Further, even if the FDA lifts the clinical hold, or if the FDA or other regulatory agencies continue to express safety concerns after the hold is lifted, future preclinical or clinical studies involving CTI-1601 may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. In such instances, our progress in the development of CTI-1601 may be significantly slowed and the associated costs may be significantly increased, adversely affecting our business, which could impair our ability to ultimately obtain FDA approval for CTI-1601.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report are set forth on the Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
31.1*	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1**	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS*	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tag re embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Link Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LARIMAR THERAPEUTICS, INC.

Date: August 12, 2021

By: /s/ Carole S. Ben-Maimon, M.D.
Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2021

By: /s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

I, Carole S. Ben-Maimon, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Larimar Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2021

/s/ Carole S. Ben-Maimon, M.D.

Carole S. Ben-Maimon, M.D.

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, Michael Celano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Larimar Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2021

/s/ Michael Celano

Michael Celano

Chief Financial Officer

(Principal Financial Officer and Accounting Officer)

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Larimar Therapeutics, Inc. (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

- (1) The Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2021

/s/ Carole S. Ben-Maimon, M.D.

Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2021

/s/ Michael Celano

Michael Celano
Chief Financial Officer
(Principal Financial and Accounting Officer)