

**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 March 31, 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 May 7, 2021, there were 15,367,730 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 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 (including demonstrating 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;
 - 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;
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- 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. 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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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 Reorganization (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)

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,193	\$ 68,148
Marketable debt securities	19,245	24,490
Prepaid expenses and other current assets	4,689	5,314
Total current assets	86,127	97,952
Property and equipment, net	998	1,040
Operating lease right-of-use assets	3,805	3,936
Restricted cash	1,339	1,339
Other assets	750	419
Total assets	<u>\$ 93,019</u>	<u>\$ 104,686</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,230	\$ 2,634
Accrued expenses	4,611	5,843
Operating lease liabilities, current	534	515
Total current liabilities	8,375	8,992
Operating lease liabilities	5,860	6,002
Total liabilities	<u>14,235</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 March 31, 2021 and December 31, 2020; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 15,367,730 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	15	15
Additional paid-in capital	156,470	155,290
Accumulated deficit	(77,702)	(65,614)
Accumulated other comprehensive loss	1	1
Total stockholders' equity	<u>78,784</u>	<u>89,692</u>
Total liabilities and stockholders' equity	<u>\$ 93,019</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 March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 8,974	\$ 5,007
General and administrative	3,132	1,667
Total operating expenses	12,106	6,674
Loss from operations	(12,106)	(6,674)
Other income, net	18	—
Net loss	\$ (12,088)	\$ (6,674)
Net loss per share, basic and diluted	\$ (0.76)	\$ (1.10)
Weighted average common shares outstanding, basic and diluted	15,996,133	6,091,250
Comprehensive loss:		
Net loss	\$ (12,088)	\$ (6,674)
Other comprehensive loss:		
Unrealized gain (loss) on marketable debt securities	—	—
Total other comprehensive loss	—	—
Total comprehensive loss	\$ (12,088)	\$ (6,674)

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	<u>15,367,730</u>	<u>\$ 15</u>	<u>\$ 156,470</u>	<u>\$ (77,702)</u>	<u>\$ 1</u>	<u>\$ 78,784</u>
	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	<u>6,091,250</u>	<u>\$ 6</u>	<u>\$ 32,056</u>	<u>\$ (29,806)</u>	<u>\$ —</u>	<u>\$ 2,256</u>

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)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (12,088)	\$ (6,674)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,180	29
Depreciation expense	73	23
Amortization of premium on marketable securities	(5)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	625	(11)
Accounts payable	564	(2,524)
Accrued expenses	(1,232)	230
Right-of-use assets	131	9
Operating lease liabilities	(123)	(2)
Other assets	(331)	(1)
Net cash used in operating activities:	<u>(11,206)</u>	<u>(8,921)</u>
Cash flows from investing activities:		
Purchase of property and equipment	—	(58)
Purchase of marketable securities	(1,749)	—
Maturities and sales of marketable securities	7,000	—
Merger transaction costs	—	(720)
Net cash provided by (used in) investing activities	<u>5,251</u>	<u>(778)</u>
Cash flows from financing activities:		
Capital contribution from related party	—	9,595
Offering costs	—	(18)
Net cash provided by financing activities	<u>—</u>	<u>9,577</u>
Net increase in cash, cash equivalents and restricted cash	(5,955)	(122)
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>\$ 63,532</u>	<u>\$ 887</u>
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment included in accounts payable and accrued expenses	\$ 31	\$ —
Offering costs included in accounts payable and accrued expense	\$ —	\$ 38
Merger transaction costs included in accounts payable and accrued expenses	\$ —	\$ 644
Leased assets obtained in exchange for new operating lease liabilities	\$ —	\$ 448
Payment of leasehold improvements on right-of-use assets included in operating lease liability, current	\$ —	\$ 7

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)**1. Organization, 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.

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 CTI-1601 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. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads. The extent of the effect on the Company’s operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, the impact and effectiveness of vaccines against the virus, including variants and mutations thereof, the willingness of individuals to avail themselves of the vaccines and governmental, regulatory, and private sector responses, all of which are uncertain and difficult to predict. Although the Company is unable to estimate the financial effect of the pandemic at this time, if vaccination efforts are unsuccessful or if vaccines are not efficacious against emerging or future variants of COVID-19, the Company’s business, results of operations, financial condition and cash flows could be materially and adversely affected. The financial statements do not reflect any adjustments as a result of the pandemic.

The pandemic resulted in the temporary stoppage of our CTI-1601 Phase 1 clinical trials in patients with Friedreich’s ataxia. In July 2020, we resumed these clinical trials, and have since completed dosing of both our single-ascending dose and multi-ascending dose clinical trials. We expect to release top line results from these trials in the second quarter of 2021.

The Company may 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, including as a result of resurgences of COVID-19 cases in certain geographic areas.

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 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.

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 \$12.1 million and \$6.7 million for three months ended March 31, 2021, and 2020, respectively. In addition, as of March 31, 2021, the Company had an accumulated deficit of \$77.7 million. The Company expects to continue to generate operating losses for the foreseeable future. As of March 31, 2021, the Company had approximately \$81.4 million of cash, cash equivalents and marketable securities 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. 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. Until such time, if ever, the Company expects 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.

The Company may not be able to obtain financing on acceptable terms, or at all, and it may not be able to enter into collaborations or other arrangements. There is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company, if at all, to fund continuing operations. Additionally, the terms of any financing may adversely affect the holdings or the Company's existing stockholders' rights.

The Company believes that, based on its current operating plan, its 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 its interim financial statements for the quarterly period ended March 31, 2021. If the Company does not obtain sufficient additional funding, the Company may be unable to fund operations beyond twelve months of the issuance of these financial statements.

If the Company is unable to obtain sufficient funding, the Company will delay, reduce, or eliminate some or all of its research and development programs, product portfolio expansion or pre-commercialization efforts. These actions would extend cash resources but could adversely affect the Company's business prospects. The extent and timing of implementing these cost actions will be mainly dependent on the timing and our ability to obtain additional funding. 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 contributions from Holdings. In 2020, prior to the Merger, the Company received \$18.0 million in capital contributions from Holdings. In May 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 addition, 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 could 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 December 2020, the Company sold 11,524 shares of common stock sold under the Agreement for net proceeds of \$0.2 million at an average gross price per share of \$21.89. During the first quarter of 2021, no additional sales of common stock were sold under this agreement.

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 March 31, 2021 and for the three months ended March 31, 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 March 31, 2021 and condensed consolidated results of operations and cash flows for the three months ended March 31, 2021 and 2020 have been made. The results of operations for the three months ended March 31, 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 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 March 31, 2021 and December 31, 2020, cash equivalents consisted of commercial paper, 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 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 months ended March 31, 2021 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 2,397,152 common stock equivalents, outstanding as of March 31, 2021, from the computation of diluted net loss per share for the three months ended March 31, 2021 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. Accordingly, for the three months ended March 31, 2020, there were no common stock equivalents to be excluded from the calculation of diluted net loss per share.

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 March 31, 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 upon 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 March 31, 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 March 31, 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)				
March 31, 2021				
Cash equivalents:				
Money market funds	\$ 6,922	\$ 6,922	\$ —	\$ —
Total cash equivalents	6,922	6,922	—	—
Marketable debt securities:				
Commercial paper	19,245	—	19,245	—
Total marketable debt securities	19,245	—	19,245	—
Total cash equivalents and marketable debt securities	\$ 26,167	\$ 6,922	\$ 19,245	\$ —
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 March 31, 2021 and December 31, 2020.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
(in thousands)				
March 31, 2021				
Assets:				
Commercial paper	\$ 19,245	\$ —	\$ —	\$ 19,245
	<u>\$ 19,245</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 19,245</u>
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>

As of March 31, 2021, the Company did not have an allowance for credit losses. All investments with unrealized losses at March 31, 2021 have been in a loss position for less than twelve months or the loss is not material and were temporary in nature. The Company does not intend to sell the investments that are in an unrealized loss position before recovery of their amortized cost basis.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	March 31, 2021	December 31, 2020
(in thousands)		
Prepaid research and development expenses	\$ 4,099	\$ 4,460
Prepaid insurance	367	571
Payroll tax receivable	107	32
Other prepaid expenses and other assets	116	251
	<u>\$ 4,689</u>	<u>\$ 5,314</u>

6. Fixed Assets

Fixed assets, net consisted of the following:

	Useful Life	March 31, 2021	December 31, 2020
(in thousands)			
Computer equipment	5 years	\$ 66	\$ 66
Lab equipment	5 years	849	849
Furniture and fixtures	7 years	460	460
Leasehold Improvements	lease term	31	—
		<u>1,406</u>	<u>1,375</u>
Less: Accumulated depreciation		(408)	(335)
		<u>\$ 998</u>	<u>\$ 1,040</u>

Depreciation expense during the three months ended March 31, 2021 and 2020 was \$0.1 million and less than \$0.1 million, respectively.

7. Accrued Expenses

	March 31, 2021	December 31, 2020
	(in thousands)	
Accrued research and development expenses	\$ 3,358	\$ 3,409
Accrued payroll and related expenses	459	1,350
Accrued professional fees	689	924
Accrued other	105	160
	<u>\$ 4,611</u>	<u>\$ 5,843</u>

8. Stockholders' Equity and Stock Options

Common Stock and Prefunded warrants

As of March 31, 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 an Equity Distribution Agreement (the "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 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 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 Agreement and will reimburse the investment bank for certain specified expenses. The 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 Agreement. As of March 31, 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.

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 March 31, 2021, 1,120,159 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.

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, and the remaining \$0.5 million will be 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:

	2021	2020
Risk-free interest rate	0.78%	0.37%
Expected term (in years)	6.25	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 three months ended March 31, 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	8.1	
Granted	402,550	18.70		
Forfeited	(14,300)	(20.40)		
Outstanding as of March 31, 2021	2,397,152	\$ 21.72	8.0	\$ 4.4
Exercisable as of March 31, 2021	602,463	\$ 45.48	4.0	\$ 0.8
Vested and expected to vest as of March 31, 2021	2,397,152	\$ 21.72	8.0	\$ 4.4

- (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 March 31, 2021.

January 2021 Annual Option Grant

On January 19, 2021, the Company granted options to purchase 280,150 shares of common stock to employees under the 2020 Plan. The options have an exercise price equal to the closing stock price as of the grant date, and vest over four years, with 25% vesting on the first anniversary of the grant and the remainder vesting in equal monthly installments thereafter.

Stock-Based Compensation

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Research and development	\$ 438	\$ 12
General and administrative	742	17
	<u>\$ 1,180</u>	<u>\$ 29</u>

As of March 31, 2021, total unrecognized compensation expense related to unvested stock options and restricted stock units was \$17.8 million, which is expected to be recognized over a weighted average period of 3.37 years.

9. Commitments

Intellectual Property Licenses

The Company is party to a License Agreement (the “WFUHS License”), dated November 30, 2016 with Wake Forest University Health Sciences (“WFUHS”) and a 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 months ended March 31, 2021 and 2020, 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 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 the first monthly installment of rent to be paid by the Subtenant on the date of the Sublease. After such first monthly payment, the sublease provides for rent abatement until April 1, 2021.

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 and less than \$0.1 million during the three months ended March 31, 2021 and 2020, respectively three months ended March 31, 2020. For operating leases, the weighted-average remaining lease term for leases at March 31, 2021 and December 31, 2020 was 8.3 and 8.6 years, respectively. For operating leases, the weighted average discount rate for leases at March 31, 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 March 31, 2021 are as follows:

(in thousands)	Operating Leases
Nine months ending December 31, 2021	\$ 884
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	9,689
Less: imputed interest	(3,295)
Present value of lease liabilities	\$ 6,394

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% 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% is associated with future services (see Note 8) vesting ratably over 48 months beginning on December 1, 2016. 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 months ended March 31, 2021 and 2020 the Company recognized less than \$0.1 million, 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 three months ended March 31, 2020, Holdings provided the Company non-interest bearing, permanent funding from the above Series A and Series B preferred unit transactions, totaling \$9.6 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. 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 status, 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. 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

CTI-1601 is currently being evaluated in Phase 1 clinical trials in patients with Friedreich’s ataxia. In December 2020, we announced the completion of dosing of a SAD trial of CTI-1601. A Safety Review Committee reviewed preliminary blinded data after each cohort of the placebo-controlled SAD clinical trial and recommended continuation to each escalating dose. Based on preliminary data, single subcutaneous injections of CTI-1601 at doses up to 100 mg appear to have been generally well tolerated. Injection site adverse events were mild and transient, and no serious adverse events were reported. In March 2021, we announced the completion of dosing of a MAD trial of CTI-1601. We have now completed our Phase 1 program and there are currently no patients receiving CTI-1601. We expect to release top line clinical results from the MAD trial in the second quarter of 2021.

We also have conducted several non-clinical toxicology studies, including 28 and 90-day studies in rats and non-human primates, and have an on-going 180-day non-human primate study. In the 90-day non-human primate study a mortality was observed, which was determined to be due to a bacterial meningitis infection and was unrelated to study drug. In addition, mortalities have been observed in the ongoing 180 day-non-human primate study at the highest dose levels. We have informed FDA of these findings and we are continuing to dose non-human primates in the study and are continuing to collect and evaluate data. While additional non-clinical information may be required before we initiate further clinical studies, based on all the information we have from the non-clinical program to date together with extensive input from toxicologists and other relevant experts, we currently expect to remain on-track with our previously disclosed timeline of initiating both our open-label extension (the JIVE trial) and a pediatric MAD trial in Friedreich's ataxia patients during the second half of 2021.

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 \$12.1 million and \$6.7 million for three months ended March 31, 2021, and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of \$77.7 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 approval 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 approval 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 March 31, 2021, we had cash, cash equivalents and marketable debt securities balance totaling \$81.4 million. 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 March 31, 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. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads and mutates.

In December 2020, the FDA granted emergency use authorization for two COVID-19 vaccines. Additional vaccines have since been made available. Although there are vaccines available, the ability to obtain a vaccine or know when herd immunity will be met, is difficult to project.

The extent of the effect of COVID-19 on our operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, including the spread of more contagious and deadly variants, the successful distribution and use of current and future COVID-19 vaccines, and governmental, regulatory, and other private sector responses, all of which are uncertain and difficult to predict. Although we are unable to estimate the financial effect of the pandemic at this time, if the pandemic remains uncontained or if the current vaccines prove ineffective against future viral mutations, it could have a material adverse effect on our business, results of operations, financial condition, and cash flows. The financial statements do not reflect any adjustments as a result of the pandemic.

The pandemic resulted in the temporary stoppage of our CTI-1601 Phase 1 clinical trials in patients with Friedreich's ataxia. In July 2020, we resumed these clinical trials, and have since completed dosing of both our SAD and MAD clinical trials. We expect to release top line results from these trials in the second quarter of 2021.

We may experience additional delays in clinical trial timelines as a result of additional travel and hospital restrictions related to the COVID-19 pandemic which may be imposed, including as a result of resurgences of COVID-19 cases in certain geographic areas.

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.

Research and development costs are central to our business and are expensed as incurred. 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 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 March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,		
	2021	2020	Increase (Decrease)
(in thousands)			
Statement of Operations Data:			
Operating expenses:			
Research and development	\$ 8,974	\$ 5,007	\$ 3,967
General and administrative	3,132	1,667	1,465
Total operating expenses	12,106	6,674	5,432
Loss from operations	(12,106)	(6,674)	(5,432)
Other income, net	18	—	18
Net loss	\$ (12,088)	\$ (6,674)	\$ (5,414)

Research and development expenses

Research and development expenses for the three months ended March 31, 2021 increased \$4.0 million compared to the three months ended March 31, 2020. The increase in research and development expenses as compared to the prior year period was primarily driven by higher clinical supply manufacturing costs of \$1.2 million, an increase in clinical trial costs of \$1.5 million, an increase in personnel related costs of \$0.6 million due to headcount additions in our research and development functions and an increase in stock compensation expense of

\$0.4 million associated with stock option grants made in 2020 after the merger and in the first quarter of 2021. The remaining increase is primarily related to toxicology study costs, and internal laboratory costs. During the three months ended March 31, 2021, both of the Company's SAD and MAD trials, including analysis were ongoing whereas during the three months ended March 31, 2020, only the SAD trial was on going.

General and administrative expenses

General and administrative expenses for the three months ended March 31, 2021 increased \$1.5 million compared to the three months ended March 31, 2020. The increase in general and administrative expenses as compared to the prior year period was primarily driven by an increase in insurance costs of \$0.7 million that are mainly due to the costs of operating as a public company, an increase in stock-based compensation of \$0.7 million associated with stock option grants made in 2020 after the merger and in the first quarter of 2021, an increase in personnel related costs of \$0.3 million due to increased headcount, and an increase in legal and consulting costs of \$0.3 million associated with operating as a public company. The increase is offset by a decrease in accounting and audit expense of \$0.6 million related to the additional expense incurred in 2020 associated with the Merger and becoming a public company.

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:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (11,206)	\$ (8,921)
Net cash provided by (used in) investing activities	5,251	(778)
Net cash provided by financing activities	—	9,577
Net increase in cash, cash equivalents and restricted cash	<u>\$ (5,955)</u>	<u>\$ (122)</u>

Net cash used in operating activities

During the three months ended March 31, 2021, operating activities used \$11.2 million of cash, resulting from our net loss of \$12.1 million, adjusted for noncash expenses of \$1.2 million and changes in our operating assets and liabilities of \$0.4 million. Our net loss was primarily attributed 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 accrued expenses and offset by an increase in accounts payable and prepaid expenses due to the growth in our operating activities.

During the three months ended March 31, 2020, operating activities used \$8.9 million of cash, resulting from our net loss of \$6.7 million, adjusted for noncash expenses of \$0.1 million and changes in our operating assets and liabilities of \$2.3 million. Our net loss was primarily attributed to research and development activities related to our CTI-1601 program and general and administrative expenses as described above.

Net cash provided by (used in) investing activities

During the three months ended March 31, 2021, investing activities provided \$5.3 million of cash, resulting from a \$7.0 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 three months ended March 31, 2020, investing activities used \$0.8 million of cash, resulting from Chondrial's transaction costs for the acquisition of Zafgen of \$0.7 million and \$0.1 million from the purchase of equipment.

Net cash provided by financing activities

During the three months ended March 31, 2020, net cash provided by financing activities of \$9.6 million was the result of contributions from Holdings. There was no cash used in or provided by financing activities during the three months ended March 31, 2021.

Operating Capital Requirements

CTI-1601 is currently in clinical development. We recently completed the dosing of two phase 1 clinical trials and expect to commence additional studies of CTI-1601 in Friedreich ataxia in the second half of 2021; 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 March 31, 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 quarter of 2021, no sales of common stock were sold under the ATM Agreement.

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 March 31, 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 March 31, 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 March 31, 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 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.

Topline or preliminary data from our CTI-1601 clinical trials that we announce or publish from time to time may differ materially from final data.

We have disclosed preliminary data from our single ascending dose (“SAD”) phase 1 clinical trial from CTI-1601, and we intend to disclose topline data from our multiple ascending dose (“MAD”) phase 1 clinical trial of CTI-1601 in the second quarter of 2021. Such topline, or preliminary data and any topline or preliminary data that we disclose in the future, is based on a preliminary analysis of then-available efficacy and safety data, and the results and related preliminary findings and conclusions are subject to change following a comprehensive review of the more extensive data we expect to receive related to the particular study or trial. Preliminary or topline data are based on assumptions, estimations, calculations, and conclusions as part of our analyses of data currently available to us, and we may not have received or had the opportunity to evaluate all of the data from the trial. As a result, preliminary and topline results that we report may differ from future results we report of the same studies as additional information or data become available, or we may report additional or different conclusions or considerations to qualify such results once additional data has been received and fully evaluated. Such data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously disclosed. As a result, preliminary or topline data should be viewed with caution until the final data is available. If the full data set or conclusions from the full data set are different from the topline or preliminary data reported, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain develop, obtain approval for and commercialize CTI-1601 may be harmed, which could harm our business, operating results, prospects, or financial condition.

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>
10.1	Master Services Agreement, dated as of September 20, 2017, by and between the Company and KBI Biopharma, Inc.
10.2	First Amendment to Master Services Agreement, dated as of November 9, 2018, by and between the Company and KBI Biopharma, Inc.
31.1*	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.
31.2*	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.
32.1**	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.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Link Document.

* Filed herewith.

** Furnished herewith.

+ Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

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: May 10, 2021

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

Date: May 10, 2021

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

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.



Master Services Agreement

This Master Services Agreement (this "**Agreement**") dated September 20, 2017 (the "**Effective Date**"), between **Chondrial Therapeutics, Inc.**, having a place of business at 150 Monument Road, Suite 207, Bala Cynwyd, PA 19004 ("**Client**") and KBI Biopharma, Inc., having a place of business at 1101 Hamlin Road, Durham, North Carolina 27704 ("**KBI Biopharma**") (Client and KBI Biopharma, each a "**Party**", and collectively, the "**Parties**").

Whereas, Client is engaged in the discovery and development of new biological therapeutics;

Whereas, KBI Biopharma is in the business of providing biological development and clinical manufacturing services; and

Whereas, Client desires KBI Biopharma to perform certain services in accordance with the terms of this Agreement and KBI Biopharma desires to perform such services.

Now, therefore, in consideration of the above statements, which form part of this Agreement, and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

1. Services to be Performed

- 1.1 **Scope.** KBI Biopharma shall use reasonable commercial efforts to perform the services (the "**Services**") detailed in the proposal, which has been executed by the Parties and attached hereto as Attachment One and incorporated herein by reference (the "**Proposal**"). Any deliverables to be provided to Client as a result of the performance by KBI Biopharma of the Services shall be set forth in the Proposal (the "**Deliverables**"). In the event that Client requests KBI Biopharma to perform services beyond the scope of services specifically stated in the Proposal, KBI Biopharma shall have no obligation to perform such supplemental services unless and until a Change Order is executed in accordance with Article 5 below, or unless the Parties agree in writing on a proposal for additional services to be performed under this Agreement.
- 1.2 **Additional Services.** The Parties may agree upon additional services to be performed under the terms of this Agreement, as may be described in purchase orders or proposals to be mutually agreed upon by the Parties in writing. Such additional proposals or purchase orders, when signed by both Parties, shall be included in the term "Proposal" as used in this Agreement and the additional services described therein shall be included in the term "Services" as used in this Agreement.
- 1.3 **Compliance with Laws.** As applicable to the Services, KBI Biopharma shall perform the Services in all material aspects in compliance with current cGMP and other applicable rules, regulations and guidelines of the U.S. Food and Drug Administration ("**FDA**"), as then in effect, governing the manufacture, testing and quality control of investigational drugs. For purposes of the foregoing, "**cGMP**" means the current Good Manufacturing Practices as promulgated under each of the following as in effect on the date of this Agreement and as amended or revised after the date of this Agreement and in effect at the time of the performance of the Services: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 *et seq.*) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210 and 211) and (b) the ICH guide Q7 "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" as applied to investigational drugs (Section 19). Client shall have responsibility for determining regulatory strategy and for all regulatory decisions except for those matters that KBI Biopharma, in its reasonable discretion deems contrary to

regulatory requirements of KBI or commitments made by KBI Biopharma to regulatory authorities, of which matters KBI Biopharma shall promptly notify Client in writing. Should the U.S. government regulatory requirements change, KBI Biopharma will use reasonable efforts to satisfy the new requirements. Notwithstanding the foregoing, in the event that compliance with such new U.S. regulatory requirements necessitates a change in the scope or nature of the Services to be completed, KBI Biopharma will submit to Client a Change Order in accordance with Article 5.

2. Client Obligations

- 2.1 General. Unless otherwise agreed to by the Parties in writing, in each case in accordance with the Proposal, Client is solely responsible for, and performance hereunder by KBI Biopharma is contingent upon: (a) provision of complete and accurate scientific data regarding the product which is the subject of the Proposal (the "**Product**") and such other data that is to be supplied by Client pursuant to the Proposal; (b) provision of all information necessary to effect the reliable transfer of methods to KBI Biopharma; (c) provision of specific reagents, reference standards or other materials necessary for execution of Services, as may be described in the Proposal; (d) if applicable, review and approval of in-process and finished product test results to ensure conformity of such results with required Product specifications, regardless of which Party is responsible for finished Product release; (e) preparation of all submissions to regulatory authorities for the Product; and (f) performance of all other obligations of Client set forth in the Proposal. Client shall perform its obligations as set forth in this Agreement, cooperate with KBI Biopharma in the execution of the Services and shall not engage in any act or omission, which may reasonably be expected to prevent or delay the successful execution of the Services. Such cooperation shall include, but not be limited to, informing KBI Biopharma of global regulatory strategy for development and approval of the Product to the extent relevant to the Proposal, prompt review and approval of documents requiring Client's signature, timely delivery of methods and materials and prompt response to other similar issues.
- 2.2 Provision of Regulatory Submissions. Prior to making any submission for regulatory approval of the Product, upon the request of KBI Biopharma, Client shall provide copies of all relevant parts of regulatory submissions relating to KBI Biopharma's manufacturing procedures (if applicable to the Services) to KBI Biopharma for review and reasonable opportunity to comment, provided that KBI Biopharma agrees to provide any comments within five (5) days of receipt of such information from Client.
- 2.3 Information Regarding Hazardous Materials. Client shall provide to KBI Biopharma, on an on-going basis throughout the Term (as defined below), any applicable safe handling instructions for any substance or material provided by or on behalf of Client to KBI Biopharma in sufficient time for review and training by KBI Biopharma prior to delivery of any such substance or material to KBI Biopharma. Where appropriate or required by law, Client shall provide a Material Safety Data Sheet and instructions for proper storage for all Client-provided materials, finished product and reference standards.
- 2.4 Other Company Materials. As soon as practicable following the execution of this Agreement, Client shall provide to KBI Biopharma all materials, know-how, information and technical assistance under Client's control which is associated with the Product or otherwise required for the performance of the Services in accordance with the Proposal. Client agrees that such materials, know-how, information and technical assistance shall be complete and accurate to the extent required for KBI Biopharma to perform the Services. Client hereby grants to KBI Biopharma during the Term of this Agreement the right to use any and all patent rights, trade secrets, intellectual property and other materials under Client's control to the extent useful for KBI Biopharma to perform the Services.

3. Performance

- 3.1 Schedule. Due to the unpredictable nature of biological processes, the timelines and schedules for the performance of the Services (including without limitation the dates for production and delivery of Product) and the yield or quantity of Product as set out in the Proposal are estimates only. KBI Biopharma shall keep Client regularly informed in writing of any such changes that are necessary to the Proposal, and agrees that such changes will be made to the minimum extent reasonably necessary. Client shall not be entitled to cancel any unfulfilled part of the Services or refuse acceptance of Product related to the Proposal on grounds of late performance of the Services or late delivery of the Product subject to the provisions of this Section 3.1. In such event, KBI Biopharma shall not be liable for any loss, damage, costs or expenses of any nature, whether direct, indirect, incidental or consequential, arising out of any delay in performance or delivery howsoever caused or arising out of any failure to produce the estimated quantities of Product for delivery on the estimated schedule. KBI Biopharma shall not delay or reschedule a Client manufacturing run for any reasons other than those expressly set forth in this Agreement, such as Client's breach, non-payment, or technical difficulties.
- 3.2 Technical Difficulties. If it becomes apparent to either KBI Biopharma or Client at any stage in the provision of any Services that, as a result of scientific or technical reasons out of the reasonable control of either Party, it will not be possible to complete the Services in the manner described in this Agreement or the Proposal or any Change Order thereto, the Parties will (a) identify the problem, (b) submit the problem in writing to senior management of each Party, and (c) negotiate in good faith for a thirty (30) day period from the date senior management of the Parties first convene regarding how to resolve such problem in a commercially reasonable manner. If the Parties do not agree on a commercially reasonable resolution to the problems within such thirty (30) day period, KBI Biopharma and Client shall each have the right to terminate this Agreement by written notice to the other Party, subject to Section 24.2.
- 3.3 Quality Agreement. In the event that the Proposal specifically enumerates Services that include the performance of activities that are subject to cGMP, contemporaneously with the execution of this Agreement, or as soon as practicable after the execution hereof, the Parties shall develop and agree upon a quality agreement describing the regulatory and compliance roles and responsibilities of each Party, including without limitation, procedures for handling Product recalls and non-conforming Product, the format and content of which shall be agreed upon by the Parties (the "**Quality Agreement**"). Upon execution by both Parties, the Quality Agreement shall be incorporated herein and attached hereto as Attachment Two.
- 3.4 Non-Conforming Services. Within [***] of delivery of the Product or Services, Client shall inform KBI Biopharma of any material non-conformity with required specifications set forth in the Proposal, as may be further provided in the Quality Agreement. Additionally, KBI Biopharma may identify a material non-conformity during production of the Product or execution of the Services. In the event that such non-conformity is attributable to a breach of KBI Biopharma's obligations under this Agreement or to gross negligence or willful misconduct in KBI Biopharma's execution of the services, then, as Client's sole and exclusive remedy, KBI Biopharma shall, subject to Client providing the replacement Client-supplied source materials and/or the cost thereof, as applicable, re-perform such non-conforming Services as soon as possible with no additional fees to Client.

4. **Work Output**

All reports specified in the Proposal and other applicable cGMP documentation ("**Work Output**") will be prepared using KBI Biopharma's standard format(s) unless otherwise specified in the Proposal or this Agreement. Client will be supplied with copies of Work Output generated as a result of the Services as set forth in the Proposal or Quality Agreement. All Work Output and any required Product samples will be archived by KBI Biopharma for a period of five (5) years following completion of the Services unless otherwise provided in the Proposal or required by applicable U.S. laws or regulations. At such time after, Work Output and Product samples will be sent to Client and a reasonable return fee will be charged. If Client chooses to have KBI Biopharma dispose of Work Output and Product samples, a reasonable disposal fee will be charged.

5. Change Orders

- 5.1 Change Orders. The budget for the Services specified in the Proposal and the estimated timelines specified therein are subject to the assumptions stated in the Proposal. The assumptions related to the design and objectives of the Proposal, manpower requirements, timing, capital expenditure requirements, if any, and other matters relating to the completion of the Services shall be set forth in the Proposal ("**Proposal Assumptions**"). KBI Biopharma also assumes that Client will cooperate and fully perform its obligations under this Agreement and the Proposal in a timely manner, that no event outside of KBI Biopharma's control will occur (including without limitation a Force Majeure Event), and that there are no adverse changes to any applicable laws, rules or regulations relating to the performance of the Services (the foregoing assumptions together with the Proposal Assumptions, collectively, the "**Assumptions**"). In the event of a failure of any of the Assumptions, the objectives of the Proposal cannot be achieved based on the Assumptions, or Client requests a change to the Proposal, then the scope of services to be performed shall be amended as provided in this Article 5 (a "**Modification**"). Modifications shall also arise in the event (i) Client revises KBI Biopharma's responsibilities, the specifications, the Proposal instructions, procedures, Assumptions, processes, test protocols, test methods, or analytical requirements; or (ii) Client's requirements or any Client provided information is inaccurate or incomplete.
- 5.2 Change Order Process. In the event a Modification is requested by Client or by KBI Biopharma, within ten (10) business days KBI Biopharma shall provide Client with a change order containing a complete description of the required Modifications to the budget, activities and/or duration specified in the Proposal ("**Change Order**"). Client and KBI Biopharma shall negotiate in good faith for a period of ten (10) business days following receipt of such Change Order by Client (the "**Change Order Negotiation Period**") to agree on a Change Order that is mutually acceptable. If practicable, and agreed to by Client, KBI Biopharma shall continue work on the Services during any such negotiations, but shall have no obligation to commence work with respect to any Change Order unless authorized in writing by Client. In the event the Parties are unable to agree upon such Change Order within the Change Order Negotiation Period, either Party may elect to terminate this Agreement, or if reasonably possible, to agree that KBI Biopharma will continue to perform the Services without regard to the unresolved Change Order; provided, however, that the estimated timelines shall be adjusted to reflect any delay during the Change Order Negotiation Period. In the event that this Agreement is so terminated, the provisions with respect to the effect of termination set forth in Section 24.5 shall apply. Any disputes arising from this Section 5.2 shall be resolved in accordance with the dispute resolution procedures set forth in Article 22.
- 5.3 Regulatory Changes. Notwithstanding the foregoing, with respect to any changes or modifications to the Proposal, Services or Product specifications dictated by the FDA or other applicable law or authority, Client shall be responsible for the costs of making such changes (including without limitation capital costs), validating the manufacturing process after any such change is made, and any increases in the cost of manufacturing the Product or provision of Services as a result of such change. With respect to any such changes dictated by the FDA or other applicable law or authority, the Parties will promptly meet to discuss the actions necessary to comply with such changes and the costs associated therewith. If, after reasonable efforts, the Parties are unable to agree on such changes (including the costs payable by Client pursuant to this Section 5.3), or if KBI Biopharma is unable to comply with such changes or modifications through the exercise of commercially reasonable efforts, KBI Biopharma or Client may, in its sole discretion, terminate this Agreement upon written notice to the other Party.
- 5.4 Non-Material Changes. Notwithstanding the foregoing, Client acknowledges, however, that KBI Biopharma is given flexibility to conduct the Services, although not expressly stated in the Proposal, at the time and in the manner that KBI Biopharma deems reasonably necessary to fulfill its obligations under this Agreement. Such flexibility includes the right to make non-Material Changes to the Services and the Proposal, provided that KBI Biopharma implements all such changes only (a) in accordance with KBI Biopharma's written standard operating procedures governing change control and (b) after confirming that such change does not affect the related Product specifications

and requirements if such specifications and requirements are fixed in writing by the Parties. As used herein, "**Material Change**" is defined as any variation, alteration or modification of activities, materials, or methods provided in the Proposal that (i) impacts the regulatory commitments or filings for the Product, (ii) affects the quality, purity, identity or strength of the Product, or (iii) materially increases the cost of or timelines for manufacturing the Product.

6. Compensation

- 6.1 Fees and Invoices. In consideration for KBI Biopharma performing the Services, Client shall pay to KBI Biopharma such amounts as described in the Price and Payment Terms section of the Proposal and as otherwise described in this Agreement. Following payment of an initial fee as provided in Section 6.2, the remainder of the service fees may be invoiced by KBI Biopharma monthly based on a billing schedule derived from the Proposal. Payments are due thirty (30) days from date of invoice issuance, except as specifically provided in this Agreement. Charges for materials may be invoiced to Client and are payable at the time that KBI Biopharma orders such materials for Client's project. Client agrees to pay to KBI Biopharma the cost of materials, consumables, and third party services (if described in the Proposal or otherwise approved in advance by Client as provided in Section 23.2) plus [***] to compensate KBI Biopharma for the cost of purchasing, material handling, inventory and administration and management of third party services necessary for KBI Biopharma to perform the Services. Late payments are subject to an interest charge of [***] per month or, if less, the maximum legal interest rate per month. Failure to bill for interest due shall not be a waiver of KBI Biopharma's right to charge interest. All payments are non-refundable. If paid by wire transfer, any applicable wire transfer fees must be included in the payment issued to KBI Biopharma. Client shall be responsible for, and shall promptly pay to KBI Biopharma upon demand, all costs and expenses (including without limitation reasonable attorneys' fees and court costs) incurred by KBI Biopharma in connection with the collection of payments due under this Agreement. Unless within thirty (30) days of the date of invoice, Client has advised KBI Biopharma in good faith and in writing the specific basis for disputing an invoice, Client's failure to promptly pay an invoice may, at KBI Biopharma's election, constitute a material breach of this Agreement, and in addition to other remedies available to KBI Biopharma under Section 24.3, KBI Biopharma shall be entitled to suspend performance of Services until Client has paid any past due invoices.
- 6.2 Start-up Payment. KBI Biopharma requires payment of an initial fee as specified in the Proposal, prior to commencement of Services, and before KBI Biopharma will begin facilities preparation and resource allocation commitments with respect to Client's project(s). Initial fees are due upon execution of this Agreement or the applicable Proposal, whichever occurs later. The initial fee shall be applied to the final project invoice. Upon termination of a Proposal or this Agreement, any remaining portion of the initial fee shall be applied to all outstanding amounts due from Client under the applicable Proposal. Unless otherwise provided in this Agreement or the applicable Proposal, initial fees are non-creditable and nonrefundable to any Services other than under the applicable Proposal. Client shall be entitled to apply the balance of initial fees paid for a terminated Proposal toward the initial fee payment for a subsequent Proposal for Services initiated within twelve months of the conclusion of Services under the terminated Proposal.
- 6.3 Client Delays. KBI Biopharma has allocated resources to the Services that may be difficult or impractical to reallocate to other programs in the event of a delay attributable to Client's failure to comply with its obligations under this Agreement, Client's written request for delay or scientific or technical issues related to Client's Product which are outside of KBI Biopharma's control. In recognition of this, KBI Biopharma shall be entitled to charge reasonable wind down and restart fees resulting from such delayed Services other than the cancellation or postponement of a cGMP manufacturing run, not to exceed [***] of the Services fees in the applicable Proposal (Service fees in the applicable Proposal are to be calculated as fees for the Services that were delayed minus all amounts already paid for the Services that were delayed). Where the Services include manufacturing Services for cGMP batches, in the event that Client cancels or postpones a

manufacturing run (based on the manufacturing slots reserved for Client in the most recent schedule provided to Client) for any reason other than a material breach of this Agreement by KBI Biopharma, or in the event that a manufacturing run is cancelled or postponed for scientific or technical issues related to Client's Product which are outside of KBI Biopharma's control, Client shall pay KBI Biopharma, upon receipt of an invoice, the following amounts, less all amounts already paid to KBI Biopharma for the applicable manufacturing Services:

- (i) [***] of the price of the Services for the applicable manufacturing run if such cancellation or postponement occurs [***] prior to the scheduled vial thaw date (as communicated by KBI Biopharma to Client in writing) or at any time following the scheduled vial thaw date;
 - (ii) [***] of the price of the Services for the applicable manufacturing run if such cancellation or postponement occurs from [***] prior to the scheduled vial thaw date; or
 - (iii) [***] of the price of the Services for the applicable manufacturing run if such cancellation or postponement occurs from [***] prior to the scheduled vial thaw date.
 - (iv) [***] of the price of the Services for the applicable manufacturing run if such cancellation or postponement occurs from [***] prior to the scheduled vial thaw date.
- [***]

6.4 Taxes. Any federal, state, county or municipal sales or use tax, excise tax, customs charges, duties or similar charge, or any other tax assessment (other than that assessed against KBI Biopharma's income), license, fee or other charge lawfully assessed or charged on the manufacture, sale or transportation of Product sold or Services performed pursuant to this Agreement, and all government license filing fees and, if applicable, Prescription API User (PDUFA) annual establishment fees assessed to Client by FDA with respect to all Products and Services shall be paid by Client.

7. Confidentiality

7.1 Confidential Information. During the Term and for a period of five (5) years thereafter, each Party shall maintain in confidence all information and materials of the other Party disclosed or provided to it (the "**Recipient**") by the other Party (the "**Disclosing Party**") including the terms and conditions (but not the existence) of this Agreement. Confidential information shall be identified as confidential in writing or, if disclosed verbally or by observation, summarized in writing and submitted to Recipient within thirty (30) days of the oral or visual disclosure thereof (together with all embodiments thereof, the "**Confidential Information**"); provided, however, (a) information need not be labeled or marked "confidential" or, if disclosed verbally or by observation, summarized in writing, to be deemed Confidential Information hereunder, if under the circumstances it is, or should be, understood to be confidential; and (b) information learned, observed or obtained by Client during any visit to KBI Biopharma's facilities shall be deemed "Confidential Information" of KBI

Biopharma hereunder, regardless of whether such information is marked "confidential" or subsequently summarized in writing.

7.2 Exceptions. Notwithstanding the foregoing, Confidential Information shall not include that portion of information or materials that the Recipient can demonstrate by contemporaneous written records was:

- (i) known to the public at the time of its disclosure to the Recipient, or thereafter became generally known to the public, other than as a result of actions or omissions of the Recipient in violation of this Agreement;
- (ii) disclosed to the Recipient on an unrestricted basis from a source unrelated to the Disclosing Party and not known by the Recipient to be under a duty of confidentiality to the Disclosing Party, as evidenced by competent written proof; or
- (iii) independently developed by the Recipient, or known by the Recipient prior the date of disclosure by the Recipient, without the use of Confidential Information of the Disclosing Party, as evidenced by competent written proof.

7.3 Additional Protections. Each Party shall take all reasonable steps to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those that such Party takes to protect its own information and materials of a similar nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement. All Confidential Information of a Party, including all copies and derivations thereof, is and shall remain the sole and exclusive property of the Disclosing Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than to those of its directors, officers, employees, independent contractors, and external advisors directly concerned with the carrying out of this Agreement, on a strictly applied "need to know" basis, provided that any such disclosure is made subject to obligations of confidentiality no less stringent than the obligations provided herein.

7.4 Permitted Disclosures. The obligations set forth in this Article 7 shall not apply to the extent that Recipient is required to disclose information by law, judicial order by a court of competent jurisdiction, or the rules of a securities exchange or requirement of a governmental agency for purposes of obtaining approval to test or market Product, or disclosures of information to a patent office for the purposes of filing a patent application as permitted in this Agreement; provided, however, that the Recipient shall provide prior written notice thereof to the Disclosing Party and sufficient opportunity for the Disclosing Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefore. Any disclosure permitted pursuant to this Section 7.4 shall not be considered an exception under Section 7.2.

7.5 Injunctive Relief. The Parties acknowledge that either Party's breach of this Article 7 may cause the other Party irreparable injury for which it may not have an adequate remedy at law. In the event of a breach, the non-breaching Party shall be entitled to seek injunctive relief in addition to any other remedies it may have at law or in equity, in accordance with Article 21.

8. Inventions

8.1 Inventions. KBI Biopharma agrees to promptly disclose to Client any and all data, results, ideas, information, developments, and inventions that are Product improvements, or improvements to Client Materials discovered by KBI Biopharma employees as a result of performing the Services under this Agreement ("**Product Invention**"). Such disclosure of any Product Invention by KBI Biopharma to Client will, at no additional cost, assign to Client all such Product Inventions. If Client requests and at Client's expense, KBI Biopharma will execute any and all applications,

assignments or other instruments and give testimony which shall be necessary to apply for and obtain letters of patent of the US or of any foreign country with respect to the Product Invention and Client shall compensate KBI Biopharma for the time devoted to such activities and reimburse it for expenses incurred. For Product Inventions assigned pursuant to this section, Client shall provide KBI Biopharma a royalty-free license to use such Product Inventions to the extent necessary to perform the Services.

8.2 Process Technology and Process Inventions. Notwithstanding the foregoing, Client acknowledges that KBI Biopharma possesses and shall retain full ownership of information and technology relating to general manufacturing and analytical methods and processes, ("**Process Technology**") and KBI Biopharma shall retain all rights to any data, ideas, know-how, information, developments, and inventions related to the Process Technology that are developed, conceived or reduced to practice in connection with the Services which can be generally applied to the production of biologics other than the Product and which do not use, reference, rely on or incorporate Client Materials (collectively, "**Process Inventions**").

8.3 Process Technology and Process Inventions License. For Process Technology and Process Inventions, KBI Biopharma hereby grants to Client a perpetual, world-wide, royalty-free, non-exclusive license for Client to use such Process Technology and/or Process Inventions to manufacture or have manufactured the Product. If KBI Biopharma requests, and at KBI Biopharma's expense, Client will execute any and all applications, assignments or other instruments and give testimony which shall be necessary to apply for and obtain letters of patent of the US or of any foreign country with respect to the Process Inventions and KBI Biopharma shall compensate Client for the time devoted to such activities and reimburse it for expenses incurred.

8.4 Client Materials. All Client Materials that KBI Biopharma may have access to in order to perform the Services shall be owned exclusively by the Client. Nothing in this Agreement shall be deemed to grant any rights to KBI Biopharma in any Client Materials, other than the right for KBI Biopharma to use such Client Materials to perform the Services. For the purposes hereof, "**Client Materials**" means all Client proprietary materials and information, intellectual property and developments, including without limitation, all patents, patent applications, know-how, inventions, designs, concepts, technical information, manuals, or instructions which, as of the Effective Date, are owned, licensed or controlled by Client relating to the development, formulation, manufacture, processing, packaging, analysis or testing of the Product. In the event that Client loses or forfeits its rights in such proprietary Client Materials during the Term of this Agreement for any reason, Client shall provide notice of same to KBI Biopharma immediately and this Agreement shall be subject to immediate termination by KBI Biopharma at that time, subject to Section 24.2.

9. Use of Intellectual Property Rights

Except as expressly stated in this Agreement, no intellectual property rights of any kind or nature are conveyed by this Agreement and neither Party shall have any right, title or interest in or to the other Party's intellectual property rights for any purpose whatsoever without such other Party's prior written consent.

10. Facility Visits and Audits

10.1 Scope of Visit. Client shall have the right, upon no less than thirty (30) days' prior written notice to KBI Biopharma, to visit KBI Biopharma and during regular business hours to observe the progress of the Services (i.e., person in the plant) and to inspect related records and data for the purpose of making quality control inspections so as to assure compliance with this Agreement. Client shall also have the right to perform "for cause" audits to address cGMP quality issues upon no less than ten (10) days' notice to KBI Biopharma. The form, participants, duration and procedures of all visits shall be subject to KBI Biopharma's reasonable approval.

10.2 Client Obligations. It shall be the duty of Client to follow KBI Biopharma's reasonable safety rules while in, on or about KBI Biopharma's premises. In addition, Client agrees that it and its subcontractors,

employees, representatives, and guests of any of them shall: (a) be subject to the nondisclosure obligation described in Article 7, (b) follow such security and facility access procedures as are designated by KBI Biopharma, (c) be accompanied by a KBI Biopharma representative, (d) not enter areas of any KBI Biopharma facility at times when any third party's products are being manufactured to assure protection of KBI Biopharma's or third party's confidential information, (e) stay within the areas of KBI Biopharma's facilities designated for the visit and shall not visit areas of the facility other than those areas necessary for the performance of the facility visit provided for herein without KBI Biopharma's prior written permission, and (f) use good faith efforts to avoid disrupting KBI Biopharma's operations. All information learned, observed or obtained by Client during any visit to KBI Biopharma's facilities shall be deemed "Confidential Information" of KBI Biopharma under Article 7, regardless of whether such information is marked "Confidential" or subsequently summarized in writing. Client warrants that it, and its subcontractors, employees, agents, representatives, and any personnel acting on behalf of Client hereunder who visit the KBI Biopharma facility: (i) are not debarred, under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992, as each may be amended from time to time, and (ii) will at all times comply with all safety and security regulations in effect from time to time and communicated by KBI Biopharma, and (iii) will at all times comply with Article 7 with respect to the confidentiality and use of KBI Biopharma Confidential Information.

10.3 Costs. With the exception of "for cause" audits which may be conducted as needed, Client may conduct one (1) such quality assurance facility visit per calendar year using no more than two (2) auditors for a maximum of two (2) days at no cost to Client. Additional audits will be invoiced separately on a time and materials basis at the then current rate for such services.

11. Regulatory Inspections

11.1 General. KBI Biopharma will promptly notify Client of any regulatory inspections directly relating to the Services (including related to the facilities utilized for the Services), in accordance with the terms of the Quality Agreement (if applicable). KBI Biopharma agrees to reasonably cooperate with all regulatory authorities and submit to reasonable inspections by such authorities.

11.2 Costs. Client shall be responsible for, and shall promptly pay, all documented costs charged by a regulatory authority for inspections directly related to the Services to be provided in the Proposal. KBI Biopharma's costs in connection with regulatory inspections will be invoiced separately on a time and materials basis at the then current rate for such services.

12. Warranties

12.1 Warranties of KBI Biopharma.

12.1.1. As of the Effective Date, KBI Biopharma represents and warrants to Client that it has all requisite corporate power and authority to enter into and perform all of its obligations under this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action in respect thereof on the part of KBI Biopharma. Neither the execution and delivery of this Agreement nor the performance of the transactions contemplated hereby, nor compliance by KBI Biopharma with the provisions hereof, shall conflict with any obligations or agreements of KBI Biopharma to any person, contractual or otherwise.

12.1.2. KBI Biopharma warrants to Client that it will render the Services with due care, consistent with industry standards for work of a similar nature, and that to KBI Biopharma's knowledge, KBI Biopharma's Process Technology and Process Inventions will not violate or infringe on the patent or intellectual property rights of any third party.

12.1.3. KBI Biopharma represents to Client that it is not debarred, and warrants to Client that it will not knowingly use in any capacity the services of any person debarred, under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992, as each may be amended from time to time.

12.1.4. **EXCEPT AS EXPRESSLY WARRANTED IN THIS SECTION 12.1, KBI BIOPHARMA MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE SERVICES OR PRODUCT, EXPRESS OR IMPLIED, IN ANY MANNER AND EITHER IN FACT OR BY OPERATION OF LAW, AND SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR NONINFRINGEMENT. KBI BIOPHARMA MAKES NO WARRANTIES THAT THE EXECUTION OF THE SERVICES WILL RESULT IN ANY SPECIFIC QUANTITY OR AMOUNT OF PRODUCT.**

12.1.5. KBI Biopharma has warranted, in Section 12.1.2, that the Services will be rendered with due care; however, no predetermined results are assured. Client understands and agrees that the Services are experimental in nature, that biopharmaceutical process development is subject to certain inherent risks, and as such, nothing in this Agreement shall be construed as a guarantee or warranty by KBI Biopharma that the Services, the Products, the Deliverables, or the materials, data, information or other results produced in connection therewith, will meet or otherwise satisfy any of the objectives, goals or targets stated in the Proposal. Client hereby acknowledges and agrees that there is absolutely no guarantee:

- (i) that the results of the Services will be successful in any way or will be commercially exploitable, profitable or approved by any regulatory authority;
- (ii) that the Product, or any product, resulting from the Services will fulfill certain specifications or certain yields; or
- (iii) the Products, the Services and/or the results of the Services will satisfy the requirements of any regulatory agencies at the time of submission of such results to such agencies.

12.1.6. Client's sole and exclusive remedy and KBI Biopharma's sole and exclusive obligation under the warranties provided in this Agreement shall be the remedy provided in Section 3.4.

12.2 Warranties of Client.

12.2.1. As of the Effective Date, Client represents and warrants to KBI Biopharma that it has all requisite corporate power and authority to enter into and perform all of its obligations under this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action in respect thereof on the part of Client. Neither the execution and delivery of this Agreement nor the performance of the transactions contemplated hereby, nor compliance by Client with the provisions hereof, shall conflict with any obligations or agreements of Client to any person, contractual or otherwise.

12.2.2. Client represents and warrants to KBI Biopharma that it holds legal title to, or is fully entitled to provide, the materials, methods, plans, processes and other intellectual property necessary to conduct the Services.

12.2.3. Client represents and warrants to KBI Biopharma that all materials provided by Client for use in the performance of the Services shall be free of defects and contaminants and shall be fit for use in the performance of the Services.

12.2.4. Client represents and warrants to KBI Biopharma that it will hold, use and/or dispose of Product and all materials provided by KBI Biopharma in accordance with all applicable laws, rules and regulations.

12.2.5. Client represents and warrants to KBI Biopharma that no specific safe handling instructions are applicable to any substance or material provided by Client to KBI Biopharma, except as disclosed to KBI Biopharma in writing in sufficient time for review and training by KBI Biopharma prior to delivery of any such substance or material to KBI Biopharma.

13. Indemnification

13.1 Indemnification by KBI Biopharma. Subject to Section 13.2 below, KBI Biopharma will indemnify, defend and hold harmless Client and its shareholders, directors, officers, employees and agents (each, a "**Client Indemnitee**") from and against all costs, losses, expenses (including reasonable attorneys' fees) and direct damages (collectively, "**Losses**") resulting from all lawsuits, claims, demands, actions and other proceedings by or on behalf of any third party (collectively "**Claims**") to the extent arising out of or resulting from: (i) KBI Biopharma's material breach of any covenant, warranty, or a failure of any material representation made hereunder by KBI Biopharma; (ii) KBI Biopharma's gross negligence or intentional misconduct, or (iii) the infringement or alleged infringement as a result of or arising from the Process Technology or Process Inventions, as used in the Services; except in each case to the extent such Claims or Losses arise from negligence or intentional misconduct on the part of a Client Indemnitee or a breach of this Agreement by Client.

13.2 Indemnification by Client. Client will indemnify, defend and hold harmless KBI Biopharma and its shareholders, directors, officers, employees and agents (each, a "**KBI Biopharma Indemnitee**") from and against all Losses resulting from all Claims to the extent arising out of or resulting from: (i) Client's material breach of any covenant, warranty, or a failure of any material representation made hereunder by Client; (ii) Client's development (including the conduct of clinical trials in humans), handling, manufacturing, testing, storage, transportation, disposal, marketing, commercialization (including any recalls, field corrections or market withdrawals), distribution, promotion, sale or use of the Product or Deliverables (including without limitation as a result of any illness, injury or death to persons, including employees, agents or contractors of Client or damage to property); (iii) Client's gross negligence or intentional misconduct; (iv) the infringement or alleged infringement as a result of, or arising from, the Services as requested by Client the Client Materials or the Product on the intellectual property rights of a third party, except in each case to the extent such Claims or Losses arise from negligence or intentional misconduct on the part of a KBI Biopharma Indemnitee or a breach of this Agreement by KBI Biopharma.

13.3 Indemnification Procedure. If any Claim covered by Article 13 is brought:

13.3.1. the indemnified Party shall promptly notify the indemnifying Party in writing of such Claim, provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure or delay;

13.3.2. the indemnifying Party shall assume, at its cost and expense, the sole defense of such Claim through counsel selected by the indemnifying Party and reasonably acceptable to the other Party, except that those indemnified may at their option and expense select and be represented by separate counsel;

13.3.3. the indemnifying Party shall maintain control of such defense and/or the settlement of such Claim;

13.3.4. the indemnified Party may, at its option and expense, participate in such defense, and if it so participates, the indemnifying Party and the indemnified Party shall cooperate with one another in such defense;

13.3.5. the indemnifying Party will have authority to consent to the entry of any settlement or otherwise to dispose of such Claim (provided and only to the extent that an indemnified Party does not have to admit liability and such judgment does not involve equitable relief), and an indemnified Party may not consent to the entry of any judgment, enter into any settlement or otherwise to dispose of such Claim without the prior written consent of the indemnifying Party (not to be unreasonably withheld or delayed); and

13.3.6. the indemnifying Party shall pay the full amount of any judgment, award or settlement with respect to such Claim and all other costs, fees and expenses related to the resolution thereof; provided, however, that such other costs, fees and expenses have been incurred or agreed, as the case may be, by the indemnifying Party in its defense or settlement of the Claim.

14. Limitations of Liability

14.1 Notwithstanding anything herein to the contrary, KBI Biopharma's total liability for any loss, including without limitation Losses indemnifiable pursuant to Article 13, suffered by Client resulting from this Agreement, work conducted pursuant to any Proposal or any other liability of any nature, shall be limited to the payment of damages which shall not exceed [***].

14.2 **EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL (INCLUDING WITHOUT LIMITATION, LOST PROFITS), EXEMPLARY OR SPECIAL DAMAGES OF ANY TYPE, ARISING IN CONNECTION WITH THIS AGREEMENT, ANY PROPOSAL, QUALITY AGREEMENT OR ATTACHMENTS OR DOCUMENTS RELATED THERETO, WHETHER OR NOT FORESEEABLE AND WHETHER SUCH DAMAGES ARISE IN TORT, CONTRACT, EQUITY, STRICT LIABILITY, OR OTHERWISE, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.**

15. Force Majeure

Except for each Party's payment, confidentiality and indemnity obligations, the obligations of either Party under this Agreement shall be excused during each period of delay caused by matters such as acts of God, strikes, supplier delays, shortages of raw materials, power failure, government orders, sufferance of or voluntary compliance with acts of government or governmental regulation (not in existence on the Effective Date, and including without limitation, acts of the FDA or an applicable foreign equivalent), or acts of war or terrorism, which are reasonably beyond the control of the Party obligated to perform (each, a "**Force Majeure Event**"). A Force Majeure Event shall not include a lack of funds, bankruptcy or other financial cause or disadvantage. Nothing contained in this Agreement shall affect either Party's ability or discretion regarding any strike or other employee dispute or disturbance and all such strikes, disputes or disturbances shall be deemed to be beyond the control of such Party. A Force Majeure Event shall be deemed to continue only so long as the affected Party shall be using its commercially reasonable effort to overcome such condition. If either Party shall be affected by a Force Majeure Event, such Party shall give the other Party prompt notice thereof, which notice shall contain the affected Party's estimate of the duration of such condition and a description of the steps being taken or proposed to be taken to overcome such Force Majeure Event. Any delay, or invalidity in the results delivered, in the performance of the Services occasioned by any such cause shall not constitute a default under this Agreement, and the obligations of the Parties shall be suspended during the period of delay so occasioned. During any period of any Force Majeure Event, the Party that is not directly affected by such Force Majeure Event may take any reasonable action necessary to mitigate the effects of such Force Majeure Event. If any part of the Services is invalid as a result of such disability, KBI Biopharma will, upon written request from Client, but at Client's sole cost and expense, repeat that part of the Services affected by the Force Majeure Event.

16. Insurance

- 16.1 KBI Biopharma Insurance. KBI Biopharma shall secure and maintain in full force and effect throughout the Term policies of insurance for (a) workers' compensation in accordance with applicable statutory requirements, employer's liability in an amount not less than \$1,000,000, and automobile liability in an amount not less than \$1,000,000, (b) commercial general liability in an amount not less than \$2,000,000 per occurrence and \$2,000,000 in the aggregate, and (c) products liability in an amount not less than \$2,000,000 per occurrence and \$2,000,000 in the aggregate.
- 16.2 Client Insurance. Client shall secure and maintain in full force and effect throughout the Term, and for a period of three (3) years after completion of any clinical trials in which any Product provided under this Agreement is used, policies of insurance for (a) workers' compensation in accordance with applicable statutory requirements, employer's liability in an amount not less than [***], and automobile liability in an amount not less than [***], (b) primary and noncontributory commercial general liability in an amount not less than [***] per occurrence and [***] in the aggregate, (c) primary and noncontributory products/completed operations liability in an amount not less than [***] per occurrence and [***] in the aggregate, and (d) primary and noncontributory umbrella liability in an amount not less than [***] per occurrence and [***] in the aggregate provided that Chondrial shall not be required to procure the coverage described in clauses (b), (c) and (d) above until commencement of the first clinical trial using the Product in humans.

17. Independent Contractor; Non-Solicitation

- 17.1 Independent Contractor. KBI Biopharma shall perform the Services as an independent contractor of the Client. The relationship between the Parties shall not constitute a partnership, joint venture or agency nor constitute either Party as the agent, employee or legal representative of the other. The Parties agree that neither shall have power or right to bind or obligate the other, nor shall either hold itself out as having such authority.
- 17.2 Non-Solicitation. During the Term of this Agreement and for [***] thereafter, each Party agrees not to directly or indirectly solicit to hire or hire (in any capacity) any person who is an employee, contractor, consultant or representative of the other Party; provided that newspaper, internet or other advertisements to fill job openings shall not be deemed to be "solicitation" hereunder. Any exceptions to this provision must be in writing and signed by each Party and, for each person that is hired in such manner, the hiring Party shall compensate the other Party at the rate of [***] of such person's annualized base salary.

18. Publicity

Either Party may only issue press releases or public disclosures describing the Services provided hereunder with the prior written consent of the other Party. The use of the name, trademark, logo, or other identifying materials of either Party or its employees in any publicity, advertising or promotional material shall require the other Party's express prior written consent.

19. Shipment

- 19.1 General. Unless otherwise agreed in writing by the Parties, all Deliverables, products, raw materials, samples components or other materials provided hereunder by KBI Biopharma shall be made available for shipment Ex Works (INCOTERMS 2010) KBI Biopharma's facilities. For purposes of clarification, Ex Works means that carriage of goods shall be arranged by Client, and the cost of such carriage and risk of loss shall transfer to Client when the goods have been made available for shipment at KBI Biopharma's facilities. KBI Biopharma shall package for shipment

such product, raw materials, samples, components or other materials at Client's expense (including insurance) and in accordance with Client's reasonable written instructions.

- 19.2 Shipping Charges. Client shall pay to KBI Biopharma, in addition to actual shipping costs, a handling fee of [***] for each standard shipment of any Deliverables, products, raw materials, samples, components or other materials provided hereunder.

20. Notices

Any notice required to be given pursuant to the terms and provisions hereof shall be in writing and shall be sent by certified or registered mail, postage prepaid with return receipt requested, or by nationally recognized overnight courier, postage prepaid with return receipt requested, or by confirmed facsimile (with printed confirmation of receipt), to the other Party at the following address:

If to Client:

Chondrial Therapeutics, Inc.
150 Monument Road Suite 207
Bala Cynwyd, PA 19004
Attention: Vice President Regulatory Affairs and Counsel

With a copy to the Chief Executive Officer, at the same address.

If to KBI Biopharma:

KBI Biopharma, Inc.
1101 Hamlin Road
Durham, North Carolina 27704
Attention: Vice President Finance

with a copy to the Vice President and General Counsel, at the same address.

Each notice shall be deemed sufficiently given, served, sent, or received for all purposes at such time as it is delivered to the addressee or at such time as delivery is refused by the addressee upon presentation.

21. Choice of Law

This Agreement shall be construed and enforced in accordance with the laws of and in the venue of the State of Delaware, without regard to its, or any other jurisdiction's, rules regarding conflicts or choice of laws. The Parties waive application of the provisions of the 1980 U.N. Convention on Contracts for the International Sale of Goods, as amended.

22. Dispute Resolution

- 22.1 Initial Attempts to Resolve Disputes. If a dispute arises between the Parties in connection with this Agreement, the respective presidents or senior executives of KBI Biopharma and Client shall first meet as promptly as practicable and attempt to resolve in good faith such dispute. If such parties cannot resolve the dispute within thirty (30) days after written notice given by one Party to the other specifically invoking this stage in the dispute resolution procedure, either Party may by written notice to the other commence the arbitration process set forth in Section 22.2 below.

- 22.2 Arbitration. If a dispute has not been resolved by negotiation as provided in Section 22.1 above, then, except as otherwise provided in this Section 22.2, the dispute will be finally settled by binding arbitration in accordance with the Commercial Arbitration Rules of the AAA then in effect, by three (3) arbitrators, one of whom will be designated by each Party and the third of whom will be

designated by the two so designated. The arbitration, it shall be conducted in English and held in Delaware. The arbitrators will render their award in writing and, unless all Parties agree otherwise, will include an explanation in reasonable detail of the reasons for their award. Judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The Parties expressly waive any putative right they may otherwise have to seek an award arising out of any dispute hereunder of punitive damages or any other damages limited or excluded by this Agreement. The arbitrator will have the authority to grant injunctive relief and other specific performance. The arbitrator will, in rendering its decision, apply the substantive law of the State of Delaware, without regard to its conflict of laws' provisions. The decision and/or award rendered by the arbitrator will be final and non-appealable (except for an alleged act of corruption or fraud on the part of the arbitrator).

22.3 **Expenses.** All expenses and fees of the arbitrators and expenses for hearing facilities and other expenses of the arbitration will be borne equally by the Parties unless the Parties agree otherwise or unless the arbitrators in the award assess such expenses against one of the Parties or allocate such expenses other than equally between the Parties. Each of the Parties will bear its own counsel fees and the expenses of its witnesses except (i) to the extent otherwise provided in this Agreement or by applicable law or (ii) to the extent the arbitrators in their discretion determine for any reason to allocate such fees and expenses among the Parties in a different manner. Any attorney or retired judge who serves as an arbitrator will be compensated at a rate equal to his or her current regular hourly billing rate unless otherwise mutually agreed upon by the Parties and the arbitrator.

22.4 **Interlocutory Relief.** Compliance with this Article 22 is a condition precedent to seeking relief in any court or tribunal in respect of a dispute, but nothing in this Article 22 will prevent a Party from seeking interlocutory relief in the courts of appropriate jurisdiction provided in Article 21, pending the arbitrator's determination of the merits of the controversy, if applicable to protect the Confidential Information, property or other rights of that Party. For such disputes, the Parties agree to and submit to the sole and exclusive jurisdiction of the Delaware courts, both state and federal.

23. Assignment and Delegation

23.1 **Assignment.** This Agreement between the Parties shall not be assigned in whole or in part by either Party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed; provided, however, either Party may assign this Agreement in its entirety without the other Party's consent, upon written notice to the other Party, as part of: (a) the sale of all or substantially all of the assets or the entire business to which this Agreement relates, (b) the license by Client to a third party of rights to any Product, or (c) a merger, consolidation, reorganization or other combination with or into another person or entity, in each case, pursuant to which the surviving entity or assignee assumes in writing the assigning or merging Party's obligations hereunder. Any attempt to assign, or purported assignment of, this Agreement in contravention to this Section 23.1 shall be void *ab initio* and of no effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

23.2 **Delegation.** Neither Party may delegate any performance under this Agreement; however, performance of the Services hereunder may be delegated or subcontracted by KBI Biopharma with the written consent of Client, which consent shall not be unreasonably withheld.

24. Term and Termination

24.1 **Term.** The term of this Agreement (the "**Term**") shall be from the Effective Date until the fifth anniversary thereof, unless extended or earlier terminated as provided herein. If the Services have not been completed at the end of the initial term, the Term will thereafter be extended for successive one year periods until the Services have been completed. Additionally, the Agreement may be terminated sooner as provided in Section 24.2 or 24.3, or the Term may be extended by

written agreement of the Parties. KBI Biopharma and Client each agree that, if Client's efforts to develop a Product are successful, they will use commercially reasonable and good faith efforts to negotiate an extension of the Term to include commercial scale Product manufacturing in the Services to be provided by KBI Biopharma.

- 24.2 Termination without Breach. Client may terminate this Agreement or a Proposal prior to completion of the Proposal by providing thirty (30) days written notice to KBI Biopharma, subject to the conditions of this Section 24.2. Upon receipt of such notice of termination, KBI Biopharma will promptly scale down the affected portion of the Proposal and use reasonable commercial efforts to avoid (or minimize, where non-cancellable) additional expenses. It is understood between the Parties that KBI Biopharma will incur substantial costs for reservations of resources and planning in order to undertake the provision of Services. Therefore, in the event that this Agreement or a Proposal is terminated for any reason other than (i) by Client for KBI Biopharma's material breach in accordance with Section 24.3 or (ii) by Client in accordance with Section 24.4, Client shall pay KBI Biopharma upon receipt of invoice all of its costs for Services performed and expenses incurred or irrevocably obligated related to the Proposal and any amounts due per section 6.3.
- 24.3 Termination for Breach. In the event of a material breach of this Agreement by a Party that is not cured within thirty (30) days of written notice of such breach by the non-breaching Party, the non-breaching Party may terminate this Agreement or a Proposal immediately upon written notice. Upon such termination, KBI Biopharma will promptly scale down the affected portion of the Proposal and use its reasonable commercial efforts to avoid (or minimize, where non-cancellable) additional expenses. It is understood between the Parties that KBI Biopharma will incur substantial costs for reservations of resources and planning in order to undertake the provision of Services. Therefore, in the event of termination under this Section 24.3 by KBI Biopharma, Client shall pay KBI Biopharma upon receipt of invoice all of its costs incurred or irrevocably obligated related to the Proposal and any amounts due per section 6.3. In the event of termination under this Section 24.3 by Client (i) Excluding the first initial fee payable under each proposal, KBI Biopharma shall, notwithstanding any provisions of this Agreement concerning payments being non-refundable, refund to Client any portion of amounts paid by Client to KBI Biopharma that have not been and cannot be applied to the price of Services properly performed, (ii) if requested by Client, KBI Biopharma shall continue to provide Services under the terms of this Agreement and any related Proposal and Quality Agreement (all of which shall continue in force while such Services are being performed by KBI Biopharma) until such time as the Client has an agreement in place with a replacement provider of Services and such provider is ready to provide Services, and (iii) KBI Biopharma agrees to provide knowledge transfer services and otherwise provide support for the transition of Services to such replacement provider, such transition services to be provided at KBI Biopharma's sole cost and expense.
- 24.4 Bankruptcy. This Agreement may be terminated upon written notice by a Party in the event: (i) the other Party voluntarily enters into bankruptcy proceedings; (ii) the other Party makes an assignment for the benefit of creditors; (iii) a petition is filed against the other Party under a bankruptcy law, a corporate reorganization law, or any other law for relief of debtors or similar law analogous in purpose or effect, which petition is not stayed or dismissed within sixty (60) days of filing thereof; or (iv) the other Party enters into liquidation or dissolution proceedings or a receiver is appointed with respect to any assets of the other Party, which appointment is not vacated within one hundred and twenty (120) days.
- 24.5 Effects of Termination. Upon termination of this Agreement for any reason, each Party shall, as soon as practicable, but in any event within ten (10) business days of the effective date of termination, return to the other or destroy all Confidential Information which it possesses that belongs to the other Party, except that each may retain a copy in its law department for record keeping purposes. Upon termination of this Agreement, KBI Biopharma will furnish to Client a complete inventory of all work in progress and an inventory of all Product processed pursuant to the Proposal, and completed deliverables, data, or results not yet provided to Client. Upon termination of this Agreement, neither Party shall use or exploit in any manner whatsoever any intellectual

property rights or Confidential Information of the other Party, except as may be specifically provided in this Agreement.

25. Survival

Articles 4, 7, 8, 9, 13, 14, 18, 20, 21, 22, 25, 26, and Sections 6.4, 12.2.4, 16.2, 24.2, 24.3 and 24.5 hereof shall survive termination or expiration of this Agreement. Expiration or termination shall not extinguish the rights and remedies of either Party with respect to any antecedent breach of any of the provisions of this Agreement or payments due or earned under this Agreement.

26. Severability

In the event that any one or more of the provisions of this Agreement should be held for any reason by any court or authority having final jurisdiction over this Agreement, or over any of the Parties to this Agreement, to be invalid, illegal, or unenforceable, such provision or provisions shall be reformed to approximate as nearly as possible the intent of the Parties, and if not reformable, shall be divisible and deleted in such jurisdictions; elsewhere, this Agreement shall not be affected.

27. Waiver and Remedies

The delay or waiver (or single or partial exercise) by either Party hereto of any right, power, or privilege hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right, power, or privilege hereunder or of any other breach by or failure of such other Party, whether of a similar nature or otherwise. Any such waiver must be made in writing. Except as may otherwise be specifically set forth in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law or equity. No Party shall have any right of set off with respect to amounts it has an obligation to pay hereunder. No provision of this Agreement shall in any way inure to the benefit of any third person so as to constitute to any such person a third-party beneficiary of this Agreement or otherwise give rise to any cause of action in any person not a Party hereto.

28. Entire Agreement, Amendment, Construction, Precedence

This Agreement, the Proposal(s), and any applicable Quality Agreement constitute the entire agreement between the Parties and supersede all prior and contemporaneous negotiations, representations, commitments, agreements and understandings between the Parties (whether written or oral) relating to the subject matter hereof. This Agreement may not be amended or modified without the mutual written consent of both Parties. In the event of any conflict among the components of this Agreement, the following order of precedence shall apply: (i) the terms and conditions of the Agreement, (ii) the Quality Agreement (if existing), and (iii) the Proposal. If Client chooses to issue a purchase order for the delivery of the Services or any component thereof, such purchase order should reference this Agreement and shall be issued solely for the convenience of Client and to provide subject matter description; however, any legal terms and conditions contained or referenced therein shall be of no effect.

29. Counterparts

This Agreement, the Quality Agreement(s), the Proposal(s) and any other attachment may be executed in counterparts, each of which will be deemed an original but all of which together will constitute a single instrument. A facsimile or electronic transmission of the above referenced documents, or a counterpart, shall be legal and binding on the Parties.

[Signature Page Follows.]

The Parties by their authorized representatives execute this Agreement as of the Effective Date.

KBI BIOPHARMA, INC.	CLIENT
By: <u>/s/ Tim Kelly</u>	By: <u>/s/ Carole S. Ben-Maimon</u>
Name: <u>Tim Kelly</u>	Name: <u>Carole S. Ben-Maimon</u>
Title: <u>President & CEO</u>	Title: <u>President, CEO</u>
Date: <u>20Sep2017</u>	Date: <u>9/26/17</u>
	Chondrial Legal Approved <u>/s/ Jennifer S. Johansson</u>

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.

FIRST AMENDMENT TO MASTER SERVICES AGREEMENT

This First Amendment to the Master Services Agreement ("First Amendment") executed as of the dates below and effective as of 09 November 2018, (the "First Amendment Effective Date") by and among **Chondrial Therapeutics, Inc.**, having an address at 150 Monument Road, Suite 207, Bala Cynwyd, PA 19004 ("Client") and **KBI Biopharma, Inc.** ("KBI Biopharma") with an address at 1101 Hamlin Road, Durham, North Carolina 27704.

WHEREAS, Client and KBI Biopharma entered into a Master Services Agreement ("Agreement") with an effective date of 20 September 2017 ("Agreement Effective Date"); and

WHEREAS, the parties desire to amend the Agreement as of the First Amendment Effective Date as set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements set forth in this First Amendment, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows.

1. Section 16.2 shall be modified by this Section and replacing it with the following:

Client Insurance. Client shall secure and maintain in full force and effect throughout the Term, and for a period of three (3) years after completion of any clinical trials in which any Product provided under this Agreement is used, policies of insurance for (a) workers' compensation in accordance with applicable statutory requirements, employer's liability in an amount not less than [***], and automobile liability in an amount not less than [***], (b) primary and noncontributory commercial general liability in an amount not less than [***] per occurrence and [***] in the aggregate, (c) primary and noncontributory products/completed operations liability in an amount not less than [***] per occurrence and [***] in the aggregate, and (d) primary and noncontributory umbrella liability in an amount not less than [***] per occurrence and [***] in the aggregate provided that Chondrial shall not be required to procure the coverage described in clauses (b), (c) and (d) above until commencement of the first clinical trial using the Product in humans

2. Other Terms. Unless as otherwise indicated in this Amendment, the terms and conditions of the Agreement are incorporated in and made a part of this Amendment by this reference as if restated here. All references in the Agreement to such Agreement shall be deemed to include the provisions of this Amendment.

Signatures appear on the following page

IN WITNESS WHEREOF, the Parties have caused this First Amendment to be executed by their duly authorized representatives as of the date first written above.

CHONDRIAL THERAPEUTICS, INC.	KBI BIOPHARMA, INC.
By: <u>/s/ Carole Ben-Maimon</u> [signature]	By: <u>/s/ Tim Kelly</u> [signature]
Name: <u>Carole Ben-Maimon</u>	Name: <u>Tim Kelly</u>
Title: <u>President and CEO</u>	Title: <u>President & CEO</u>
Date: <u>7/15/2019</u>	Date: <u>16Jul2019</u>

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: May 10, 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: May 10, 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 March 31, 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: May 10, 2021

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

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

Date: May 10, 2021

/s/ Michael Celano

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