

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2020

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)

20-3857670
(IRS Employer
Identification No.)

Three Bala Plaza East, Suite 506
Bala Cynwyd, PA 19004
(Address of principal executive offices, including zip code)

Registrant's Telephone Number, Including Area Code: (844) 511-9056

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	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 July 31, 2020, there were 15,356,206 shares of the registrant's Common Stock, \$0.001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), about us and our subsidiaries. These forward-looking statements are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact, and can be identified by the use of forward-looking terminology such as “believes,” “expects,” “may,” “will,” “could,” “should,” “projects,” “plans,” “goal,” “targets,” “potential,” “estimates,” “pro forma,” “seeks,” “intends” or “anticipates” or the negative thereof or comparable terminology. Forward-looking statements include, but are not limited to, statements concerning:

- 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 and nonclinical programs being developed and anticipated to be developed 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 in our anticipated clinical timelines, patient recruitment and milestones for CTI-1601, including those associated with COVID-19;
 - uncertainties in obtaining successful clinical results 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;
 - the 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;
 - the performance of third-parties upon which we depend, including third-party contract research organizations, or CROs, and third-party suppliers, manufacturers, group purchasing organizations, distributors and logistics providers;
 - our ability to maintain our relationships, profitability and contracts with our key commercial partners;
 - our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
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- our ability to comply with stringent U.S. and foreign government regulations in the manufacturing of pharmaceutical products, including good manufacturing practice compliance and other relevant regulatory authorities;
- 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 recent outbreak COVID-19, 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.

You should assume that the information appearing in this report is accurate as its date only. Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. The factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Current Report on Form 8-K/A filed on June 26, 2020, and those listed under Part II, Item 1A. Risk Factors of this Quarterly Report. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements after the date of this report for any reason, even if new information becomes available in the future.

This Quarterly Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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On May 28, 2020, Larimar Therapeutics, Inc. (formerly known as Zafgen, Inc.) (“Larimar”), completed its reverse merger with Chondrial Therapeutics, Inc. (“Chondrial”), in accordance with the terms of the Agreement and Plan of Merger, dated as of December 17, 2019, as amended, by and among Larimar, Chondrial, a wholly-owned subsidiary of Larimar, Zordich Merger Sub, Inc. (“Merger Sub”) and Chondrial Holdings, LLC (“Holdings”), the sole stockholder of Chondrial (the “Merger Agreement”), pursuant to which Merger Sub merged with and into Chondrial, with Chondrial surviving as a wholly owned subsidiary of Larimar (the “Merger”).

For accounting purposes, the Merger is treated as a “reverse asset acquisition” under generally acceptable 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.

This quarterly report on Form 10-Q relates to the Company’s quarter ended June 30, 2020, which includes the date of the completion of the Merger and is therefore the Company’s first periodic report that includes results of operations for the combined company, including Chondrial.

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>June 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 112,673	\$ 1,009
Marketable debt securities	1,011	—
Prepaid expenses and other current assets	5,427	3,741
Total current assets	119,111	4,750
Property and equipment, net	675	274
Operating lease right-of-use assets	4,252	87
Restricted cash	1,339	—
Other assets	80	90
Total assets	<u>\$ 125,457</u>	<u>\$ 5,201</u>
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,258	\$ 3,539
Accrued expenses	3,796	2,259
Operating lease liabilities, current	591	97
Total current liabilities	6,645	5,895
Operating lease liabilities	6,268	—
Total liabilities	<u>12,913</u>	<u>5,895</u>
Commitments and contingencies (See Note 9)		
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; 5,000,000 shares authorized as of June 30, 2020 and December 31, 2019; no shares issued and outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value per share; 115,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 15,356,206 and 6,091,250 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	15	6
Additional paid-in capital	153,668	22,432
Accumulated deficit	(41,136)	(23,132)
Accumulated other comprehensive loss	(3)	—
Total stockholders' equity (deficit)	<u>112,544</u>	<u>(694)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 125,457</u>	<u>\$ 5,201</u>

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

LARIMAR THERAPEUTICS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 8,907	\$ 3,128	\$ 13,914	\$ 7,350
General and administrative	2,492	576	4,159	1,078
Total operating expenses	11,399	3,704	18,073	8,428
Loss from operations	(11,399)	(3,704)	(18,073)	(8,428)
Other income, net	69	—	69	—
Net loss	\$ (11,330)	\$ (3,704)	\$ (18,004)	\$ (8,428)
Net loss per share, basic and diluted	\$ (1.21)	\$ (0.61)	\$ (2.33)	\$ (1.38)
Weighted average common shares outstanding, basic and diluted	9,381,412	6,091,250	7,736,331	6,091,250
Comprehensive loss:				
Net loss	\$ (11,330)	\$ (3,704)	\$ (18,004)	\$ (8,428)
Other comprehensive loss:				
Unrealized loss on marketable debt securities	(3)	—	(3)	—
Total other comprehensive loss	(3)	—	(3)	—
Total comprehensive loss	\$ (11,333)	\$ (3,704)	\$ (18,007)	\$ (8,428)

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

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN
STOCKHOLDERS' EQUITY (DEFICIT)

(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, 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>
Capital contributions from related party	—	—	8,400	—	—	8,400
Merger with Zafgen Inc.	3,124,337	3	37,116	—	—	37,119
Private Placement of common shares and pre-funded warrants, net of transaction costs	6,140,619	6	75,344	—	—	75,350
Stock-based compensation expense	—	—	752	—	—	752
Unrealized loss on marketable debt securities	—	—	—	—	(3)	(3)
Net loss	—	—	—	(11,330)	—	(11,330)
Balances as of June 30, 2020	<u>15,356,206</u>	<u>15</u>	<u>153,668</u>	<u>(41,136)</u>	<u>(3)</u>	<u>112,544</u>
Balances as of December 31, 2018	6,091,250	6	2,908	—	—	2,914
Capital contributions from related party	—	—	3,000	—	—	3,000
Stock-based compensation expense	—	—	34	—	—	34
Net loss	—	—	—	(4,724)	—	(4,724)
Balances as of March 31, 2019	<u>6,091,250</u>	<u>6</u>	<u>5,942</u>	<u>(4,724)</u>	<u>—</u>	<u>1,224</u>
Capital contributions from related party	—	—	2,990	—	—	2,990
Stock-based compensation expense	—	—	33	—	—	33
Net loss	—	—	—	(3,704)	—	(3,704)
Balances as of June 30, 2019	<u>6,091,250</u>	<u>\$ 6</u>	<u>\$ 8,965</u>	<u>\$ (8,428)</u>	<u>\$ —</u>	<u>\$ 543</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)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (18,004)	\$ (8,428)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	781	67
Depreciation expense	55	38
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,760)	(1,324)
Accounts payable	(3,284)	653
Accrued expenses	1,067	11
Right-of-use assets	89	39
Operating lease liabilities	(85)	(26)
Other assets	21	5
Net cash used in operating activities:	<u>(21,120)</u>	<u>(8,965)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(58)	(33)
Cash, cash equivalents, and restricted cash acquired in connection with the Merger	41,934	—
Merger transaction costs	(1,233)	—
Net cash provided by (used in) investing activities	<u>40,643</u>	<u>(33)</u>
Cash flows from financing activities:		
Capital contribution from related party	17,995	5,990
Proceeds from sale of common stock and prefunded warrants, net of issuance costs	75,485	—
Net cash provided by financing activities	<u>93,480</u>	<u>5,990</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	113,003	(3,008)
Cash, cash equivalents and restricted cash at beginning of period	1,009	4,396
Cash, cash equivalents and restricted cash at end of period	<u>\$ 114,012</u>	<u>\$ 1,388</u>
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of net assets acquired in the Merger, including \$1.0 million of marketable debt securities and excluding cash acquired	\$ (4,815)	\$ —
Leased assets obtained in exchange for new operating lease liabilities	\$ 448	\$ —
Offering costs included in accounts payable and accrued expenses	\$ 135	\$ —
Merger transaction costs included in accounts payable and accrued expenses	\$ 65	\$ —

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 biopharmaceutical company leveraging its proprietary knowledge to develop a therapeutic treatment for mitochondrial disorders which currently have no cure. The Company has focused on Friedreich’s Ataxia, which is a progressive disease that affects multiple body systems, particularly the brain and heart. CTI-1601, the Company’s lead product candidate in Phase 1 clinical development, utilizes a cell penetrant peptide to deliver frataxin, the protein deficient in Friedreich’s Ataxia, to the mitochondria where it is believed to be processed into mature frataxin and becomes active in mitochondrial metabolism.

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 and the ability to secure additional capital to fund operations. Drug candidates currently under development will require extensive nonclinical 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, 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 the pandemic continues to evolve into a severe worldwide crisis, it could have a material adverse effect on the Company’s 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 the Company’s Phase 1 clinical trial studying CTI-1601 in patients with Friedreich’s Ataxia after the completion of two cohorts. The Company has since resumed the SAD Phase 1 clinical trial in July 2020. The Company is conducting the clinical trial at one clinical trial site. Because Friedreich’s Ataxia is a rare disease, there are a limited number of patients in close proximity to the clinical trial site and clinical trial patients travel from throughout the United States to the clinical trial site to participate. After dosing, patients remain in isolation in the clinical research unit for a period of time. The travel advisories and risk of infection related to COVID-19 have presented increased risks to patients traveling to the Company’s clinical trial site for dosing and the Company expects to incur additional clinical trial costs to safely transport and isolate patients participating in the trial. While top line results from the ongoing Phase 1 clinical trials were originally expected by the end of 2020, the delay in the clinical trial timeline caused by the ongoing impact of COVID-19 resulted in top line results now being expected in the first half of 2021. The Company 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, 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) 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; and (3) existing members of Chondrial management will be 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 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. 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, Chondrial Therapeutics Inc., Chondrial Therapeutics IP LLC, Zafgen Securities Corporation, Zafgen Australia Pty Limited and Zafgen Animal Health, LLC. 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 consolidated financial statements are issued. As of the issuance date of these condensed consolidated financial statements, the Company expects that its cash and cash equivalents will be sufficient to fund its forecasted operating expenses and capital expenditure requirements for at least the next twelve months from the issuance date of these financial statements.

Since its inception, the Company has incurred significant operating losses and negative cash flows from operations. The Company has not yet commercialized any products and does not expect to generate revenue from the commercial sale of any products for several years, if at all. The Company expects that its research and development and general and administrative expenses will continue to increase and, as a result, will need additional capital to fund its future operations, which it may raise through a combination of equity offerings, debt financings,

other third-party funding, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements.

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, 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 2020, prior to the Merger, the Company received \$18.0 million in capital contributions from Holdings.

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

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The condensed consolidated balance sheet as of December 31, 2019 was derived from the Company's audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of June 30, 2020 and for the three and six months ended June 30, 2020 and 2019, 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, 2019 included in the Company's Current Report on Form 8-K/A filed on June 26, 2020. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of June 30, 2020 and condensed consolidated results of operations and cash flows for the three and six months ended June 30, 2020 and 2019 have been made. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

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 the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in these manufacturing services or in the supply of active pharmaceutical ingredients 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. Cash equivalents consisted of money market funds, U.S. government securities and corporate bonds as of June 30, 2020. As of December 31, 2019, the Company did not have cash equivalents.

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.

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 nonclinical 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, nonclinical 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 generally 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 and six months ended June 30, 2020 includes the weighted average effect of 628,403 prefunded warrants for the purchase of shares of common stock, which were issued in June 2020, and for which the remaining unfunded exercise price is \$0.01 per share.

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

The Company excluded the following common stock equivalents, outstanding as of June 30, 2020 and 2019, from the computation of diluted net loss per share for the three and six months ended June 30, 2020 and 2019 because they had an anti-dilutive impact due to the net loss incurred for the periods:

	As of June 30,	
	2020	2019
Options to purchase common stock	720,067	—
Unvested restricted common stock	6,957	—
	<u>727,024</u>	<u>—</u>

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

Recently Issued and Adopted Accounting Pronouncements

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

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

3. Merger Accounting

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

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

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

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

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

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

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

4. Fair Value Measurements and Marketable Debt Securities

Fair Value Measurements

The Company's assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2020 and December 31, 2019 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 and cash equivalents, accounts payable and accrued liabilities. For accounts payable and accrued liabilities, the carrying amounts of these financial instruments as of June 30, 2020 and December 31, 2019 were considered representative of their fair values due to their short term to maturity.

The following tables summarize the Company's cash equivalents and marketable debt securities as of June 30, 2020, there were no cash equivalents and marketable debt securities as of December 31, 2019:

	June 30, 2020			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
(in thousands)				
Cash equivalents:				
Money market funds	\$ 33,546	\$ 33,546	\$ —	\$ —
U.S. Government securities	902	—	902	—
Corporate bonds	1,977	—	1,977	—
Total cash equivalents	<u>36,425</u>	<u>33,546</u>	<u>2,879</u>	<u>—</u>
Marketable securities:				
Corporate bonds	1,011	—	1,011	—
Total marketable debt securities	<u>1,011</u>	<u>—</u>	<u>1,011</u>	<u>—</u>
Total cash equivalents and marketable debt securities	<u>\$ 37,436</u>	<u>\$ 33,546</u>	<u>\$ 3,890</u>	<u>\$ —</u>

Marketable Debt Securities

The following tables summarize the Company's marketable debt securities as of June 30, 2020. There were no marketable debt securities as of December 31, 2019:

	June 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
(in thousands)				
Assets:				
Corporate bonds (due within 1 year)	\$ 1,014	\$ —	\$ (3)	\$ 1,011
	<u>\$ 1,014</u>	<u>\$ —</u>	<u>\$ (3)</u>	<u>\$ 1,011</u>

As of June 30, 2020, the Company did not have an allowance for credit losses.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2020	December 31, 2019
(in thousands)		
Prepaid research and development expenses	\$ 4,926	\$ 3,099
Capitalized transaction costs	—	419
Research and development tax credit sale receivable	—	82
Payroll tax receivable	55	76
Other prepaid expenses and other assets	446	65
	<u>\$ 5,427</u>	<u>\$ 3,741</u>

Capitalized transaction costs as of December 31, 2019 consists of capitalized legal and proxy fees incurred by the Company, related to the Merger. These costs were included in the purchase price allocation when accounting for the Merger.

6. Fixed Assets

Fixed assets, net consisted of the following:

	Useful Life	June 30, 2020	December 31, 2019
		(in thousands)	
Computer equipment	5 years	\$ 41	\$ 14
Lab equipment	5 years	389	389
Furniture and fixtures	7 years	479	50
		909	453
Less: Accumulated depreciation		(234)	(179)
		<u>\$ 675</u>	<u>\$ 274</u>

Depreciation expense during the three and six months ended June 30, 2020 and 2019 was less than \$0.1 million.

7. Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Accrued research and development expenses	\$ 2,290	\$ 1,295
Accrued payroll and related expenses	516	119
Accrued professional fees	526	337
Accrued other	464	508
	<u>\$ 3,796</u>	<u>\$ 2,259</u>

8. Stockholders' Equity and Stock Options

Common Stock and Prefunded warrants

As of June 30, 2020, 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 our common stock.

Restricted Common Units

In November 2016, Holdings granted 123,853 Restricted Common Units of Holdings to Dr. Mark Payne (see Note 10) with an aggregate grant date fair value of approximately \$0.5 million. Thirty percent (30%) of the award vested upon issuance with the remaining seventy percent (70%) vesting ratably over the next 48 months as long as services were continued to be provided as stipulated in the consulting agreement. The Company has recognized compensation expense of less than \$0.1 million on a graded vesting basis in research and development expense during each of the three and six months ended June 30, 2020 and 2019. As of June 30, 2020, the Company expects to recognize less than \$0.1 million over the remaining five-month vesting period. In accordance with ASC 718, *Compensation—Stock Compensation*, the Company has recorded costs incurred as stock-based compensation with a corresponding capital contribution from Holdings as such employees are working on behalf of the Company.

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") were assumed by the Company. These plans are administered by the Board or, at the discretion of the Board, by a committee of the Board.

2014 Stock Option and Incentive Plan and 2006 Stock Option Plan

In 2014, the Board and shareholders of Zafgen adopted the 2014 Plan. The 2014 Plan provides 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. The number of shares reserved for issuance may be increased by the number of shares under the previously authorized 2006 Plan that are not needed to fulfill the Company's obligations for awards issued under the 2006 Plan as a result of forfeiture, expiration, cancellation, termination or net issuances of awards thereunder. The number of shares of common stock that may be issued under the 2014 Plan is also subject to increase on the first day of each fiscal year by the lesser of (i) 4% of the Company's outstanding shares of common stock as of that date, or (ii) an amount determined by the Board. As of June 30, 2020, 505,893 shares of common stock were available for grant under the 2014 Plan, including 124,821 shares of common stock automatically added to the 2014 Plan on January 1, 2020.

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 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.

During the three and six months ended June 30, 2020 Holdings did not issue options to purchase Common Units to employees of the Company. During the three and six months ended June 30, 2019 Holdings issued 59,236 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 was \$12.14 per share were substituted for the 202,392 options to purchase Common Units, with a weighted average exercise price was \$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 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:

	2020	2019
Risk-free interest rate	0.47%	2.00%
Expected term (in years)	6.25	6.25
Expected volatility	90%	77%
Dividend yield	0.00%	0.00%

Stock Options

The following table summarizes the Company’s stock option activity for the six months ended June 30, 2020:

	Number of Shares	Weighted Average Exercise Price	Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	202,392	\$ 10.36	7.5	\$ —
Assumed as part of the Merger with Zafgen	328,770	74.80		
Modification of stock options	128,426	14.96		
Granted	60,479	11.88		
Outstanding as of June 30, 2020	<u>720,067</u>	\$ 40.73	5.4	\$ 0.4
Exercisable as of June 30, 2020	<u>535,922</u>	\$ 50.34	4.2	\$ 0.2
Vested and expected to vest as of June 30, 2020	<u>720,067</u>	\$ 40.73	5.4	\$ 0.4

July 2020 Option Grants

On July 16, 2020, the Company granted options to purchase 489,295 shares of common stock to employees under the 2014 Plan. The options have an exercise price equal to \$11.90, which was 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.

In addition, on July 16, 2020 the Company granted options to purchase 735,100 shares of common stock to employees and directors under the Company's 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan was approved by the Company's Board of Directors, upon the recommendation of the Compensation Committee of the Board on July 16, 2020. The options granted to employees have an exercise price equal to \$11.90, which was 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. The options granted to directors have an exercise price equal to \$11.90, which was the closing stock price as of the grant date, and vest monthly in equal installments over three years. The Company plans to submit the 2020 Plan to the Company's stockholders for approval. If the 2020 Plan is not approved by the stockholders of the Company by July 16, 2021, the 2020 Plan and the options granted thereunder will expire.

Option Grants with market-based vesting conditions

In October 2017, Zafgen granted 45,833 common stock options that vest on the third anniversary of the grant date upon achievement by the Company of minimum common stock prices for 20 consecutive days during the period between the first anniversary of the grant date and the third anniversary of the grant date. As of the Effective Time the options had not achieved the minimum common stock prices and remain unvested.

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
Research and development	\$ 199	\$ 17	\$ 211	\$ 36
General and administrative	553	16	570	31
	<u>\$ 752</u>	<u>\$ 33</u>	<u>\$ 781</u>	<u>\$ 67</u>

As of June 30, 2020, total unrecognized compensation expense related to unvested stock options and restricted stock units was \$1.1 million, which is expected to be recognized over a weighted average period of 3.08 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 \$2.2 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 and six months ended June 30, 2020 and 2019, 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 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 at 3 Center Plaza, Boston, Massachusetts. The lease commenced on June 21, 2019 and expires after a term of approximately 124 months and the Company has an option to extend the lease for 60 additional months. 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 Company has ceased using the leased space and is actively seeking to obtain a subtenant. The right-of-use asset is being amortized to rent expense over the remaining lease term.

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.

Expense arising from operating leases was \$0.1 million during the three and six months ended June 30, 2020 and less than \$0.1 million during the three and six months ended June 30, 2019. For operating leases, the weighted-average remaining lease term for leases at June 30, 2020 and December 31, 2019 was 9.0 and 3.3 years,

respectively. For operating leases, the weighted average discount rate for leases at June 30, 2020 and December 31, 2019 was 11.0% and 12.0%, respectively. The Company has not entered into any financing leases.

Maturities of lease liabilities due under these lease agreements as of June 30, 2020 are as follows:

<u>Year Ending December 31,</u> <u>(in thousands)</u>	<u>Operating</u> <u>Leases</u>
2020 (July - December)	\$ 588
2021	1,177
2022	1,197
2023	1,146
2024	1,065
Thereafter	5,397
Total lease payments	<u>10,570</u>
Less: Imputed interest	<u>(3,711)</u>
Present value of lease liabilities	<u>\$ 6,859</u>

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. During the three and six months ended June 30, 2020 and 2019, 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 with Deerfield Private Design Fund IV, L.P., Deerfield Private Design Fund III, L.P. and Deerfield Health Innovations Fund, L.P. (together, the “Deerfield Funds”), and certain other purchasers, from inception through May 28, 2020 and the contribution of the proceeds received by Holdings on such sales to the Company in order to fund the Company’s operations.

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

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

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

During the six months ended June 30, 2020 and the year December 31, 2019, Holdings provided the Company non-interest bearing, permanent funding from the above Series A and Series B preferred unit transactions, totaling \$18.0 million and \$19.4 million, respectively, which has been 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. No contributions were made by Holdings subsequent to the Merger.

11. Subsequent Events

The Company has entered into an Equity Distribution Agreement (the “ATM Program”) with an investment banking firm, pursuant to which the Company may sell shares of its common stock through the investment banker as sales agent for aggregate proceeds of up to \$50.0 million. The Company has not sold any shares under the ATM Program.

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, or 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, 2019 included in our Current Report on Form 8-K filed with the Securities and Exchange Commission (“SEC”), on June 2, 2020, as amended on June 26, 2020. 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 Current Report on Form 8-K filed with the SEC on June 2, 2020, as amended on June 26, 2020, 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. CTI-1601 is currently being evaluated in Phase 1 clinical trials in patients with 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, the European Medicines Agency (“EMA”) Committee for Orphan Medicinal Products (“COMP”) issued a positive opinion on the Company’s application for orphan drug designation for CTI-1601. 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.

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 \$18.0 million and \$8.4 million for the six months ended June 30, 2020, and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of \$41.1 million and a cash, cash equivalents and marketable debt securities balance of \$113.7 million. These losses have resulted principally from costs incurred in connection with research and development activities, in-licensing of technology 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 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.

We believe that, based on our current operating plan, our cash and cash equivalents as of the filing date will enable us to fund operations for at least twelve months from the issuance of these interim financial statements.

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 (the “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) Chondrial’s stockholders own a substantial majority of the voting rights in the combined company, (ii) 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 (iii) existing members of Chondrial management will be 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:

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

Research and development costs are expensed as incurred. Costs for certain activities, such as manufacturing, nonclinical 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 FDA's or other regulatory authority's influence on clinical trial design;

- 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;
- 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, of our executive, finance, information technology, and other administrative functions. General and administrative expenses also include travel expenses, allocated facility-related costs not otherwise included in research and development expenses, 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 and improve our operational, financial and management systems. Additionally, as a publicly-traded company, we will incur significant additional legal, accounting and other expenses that we did not incur as a privately-held company.

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. 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 nonclinical development activities;
- contract manufacturing organizations in connection with the production of preclinical 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 that conduct and manage clinical trials 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, nonclinical 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. 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 had been 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.

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. The extent of the effect on our operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and 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 continues to evolve into a severe worldwide crisis, 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 in a single ascending dose (referred to as "SAD") Phase 1 clinical trial in patients with Friedreich's Ataxia. We have since resumed the SAD Phase 1 clinical trial in July 2020. We are conducting the clinical trial at one clinical trial site. Because Friedreich's Ataxia is a rare disease, there are a limited number of patients in close proximity to the clinical trial site and clinical trial patients travel from throughout the United States to the clinical trial site to participate. After dosing, patients remain in isolation in the clinical research unit for a period of time. The travel advisories and risk of infection related to COVID-19 have presented increased risks to patients traveling to our clinical trial site for dosing and we expect to incur additional clinical trial costs to safely transport and isolate patients participating in the trial. In addition, additional stoppages or delays in the trial could result from new developments with respect to COVID-19. While top line results from the SAD and the planned multiple ascending dose (referred to as "MAD") ongoing Phase 1 clinical trials were originally expected by the end of 2020, the delay in the clinical trial timeline caused by the ongoing impact of COVID-19 resulted in top line results now being expected in the first half 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.

Results of Operations

Comparison of three months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Increase (Decrease)
(in thousands)			
Statement of Operations Data:			
Operating expenses:			
Research and development	\$ 8,907	\$ 3,128	\$ 5,779
General and administrative	2,492	576	1,916
Total operating expenses	<u>11,399</u>	<u>3,704</u>	<u>7,695</u>
Loss from operations	(11,399)	(3,704)	(7,695)
Other income, net	69	—	69
Net loss	<u>\$ (11,330)</u>	<u>\$ (3,704)</u>	<u>\$ (7,626)</u>

Research and development expenses

Research and development expenses for the three months ended June 30, 2020 increased \$5.8 million compared to the three months ended June 30, 2019. The increase was primarily due to a \$5.0 million increase in external development costs for CTI-1601, a \$0.4 million increase in personnel related costs due to headcount additions in our research and development functions and a \$0.2 million increase in stock-based compensation due to the modification of stock-options that converted from common unit options in Holdings to options to purchase our common stock. The \$5.0 million increase in external development costs was primarily attributed to incremental costs incurred for the further development of CTI-1601. Specifically, during late 2019 the first patients were dosed in a Phase 1 SAD clinical trial of CTI-1601. The trial was ongoing during the first quarter of 2020 but was paused due to issues related to COVID-19. During July 2020, we resumed the SAD clinical trial. In addition, there was an increase in third-party manufacturing of CTI-1601 and toxicology studies for CTI-1601 during the three months ended June 30, 2020.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2020 increased \$1.9 million compared to the three months ended June 30, 2019. The increase was primarily due to a \$1.0 million increase in professional fees that is primarily due to an increase in accounting and audit fees due primarily to the Merger, an increase in legal fees associated with intellectual property filings and costs of being a public company during the three months ended June 30, 2020. The increase was also the result of a \$0.5 million increase in stock-based compensation due to the modification of stock-options that converted from common unit options in Holdings to options to purchase our common stock.

Results of Operations

Comparison of six months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Increase (Decrease)
	(in thousands)		
Statement of Operations Data:			
Operating expenses:			
Research and development	\$ 13,914	\$ 7,350	\$ 6,564
General and administrative	4,159	1,078	3,081
Total operating expenses	18,073	8,428	9,645
Loss from operations	(18,073)	(8,428)	(9,645)
Other income, net	69	—	69
Net loss	\$ (18,004)	\$ (8,428)	\$ (9,576)

Research and development expenses

Research and development expenses for the six months ended June 30, 2020 increased \$6.6 million compared to the six months ended June 30, 2019. The increase was primarily due to a \$5.4 million increase in external development costs for CTI-1601 and a \$0.7 million increase in personnel related costs due to headcount additions in our research and development functions. The \$5.4 million increase in external development costs was primarily attributed to incremental costs incurred for the further development of CTI-1601. The trial was ongoing during the first quarter of 2020 but was paused due to issues related to COVID-19. During July 2020, we resumed the SAD clinical trial. In addition, there was an increase in third-party manufacturing of CTI-1601 and toxicology studies for CTI-1601 during the six months ended June 30, 2020.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2020 increased \$3.1 million compared to the six months ended June 30, 2019. The increase was primarily due to a \$2.1 million increase in professional fees that is primarily due to an increase in accounting and audit fees due to the Merger, an increase in legal fees associated with intellectual property filings and costs of being a public company during the six months ended June 30, 2020. The increase was also the result of a \$0.5 million increase in stock-based compensation due to the modification of stock-options that converted from common unit options in Holdings to options to purchase our common stock.

Liquidity and Capital Resources

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

Cash Flows

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

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	\$ (21,120)	\$ (8,965)
Net cash provided by (used in) investing activities	40,643	(33)
Net cash provided by financing activities	93,480	5,990
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 113,003	\$ (3,008)

Net cash used in operating activities

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

During the six months ended June 30, 2019, operating activities used \$9.0 million of cash, resulting from net loss of \$8.4 million, adjusted for noncash expenses of \$0.1 million and changes in our operating assets and liabilities of \$0.6 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 six months ended June 30, 2020, investing activities provided \$40.6 million of cash, resulting from a \$41.9 million increase from our Merger, which was offset by transaction costs associated with the Merger of \$1.2 million and \$0.1 million from the purchase of equipment.

During the six months ended June 30, 2019, investing activities used less than \$0.1 million of cash resulting from purchases of laboratory equipment.

Net cash provided by financing activities

During the six months ended June 30, 2020, financing activities provided \$93.5 million of cash that was the result of the proceeds from sale of common stock and prefunded common stock warrants, net of issuance costs, from the Private Placement of \$75.5 million and contributions from Holdings of \$18.0 million.

During the six months ended June 30, 2019, net cash provided by financing activities of \$6.0 million was the result of contributions from Holdings.

Operating Capital Requirements

CTI-1601 is currently in Phase 1 clinical development, 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:

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

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. We believe that, based on our current operating plan, our cash, cash equivalents and marketable debt securities as of the filing date, we will be able to fund operations for at least twelve months.

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

Not applicable.

Item 4. Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our principal executive officer and principal financial officer have concluded that as of June 30, 2020, our disclosure controls and procedures were not effective at the reasonable assurance level due the material weakness in internal control over financial reporting previously disclosed in our Form 8-K/A dated June 26, 2020.

Notwithstanding the identified material weaknesses, management, including our principal executive officer and principal financial officer, have determined, based on the procedures we have performed, that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q fairly represent in all material respects our financial condition, results of operations and cash flows at June 30, 2020 and for the periods presented in accordance with U.S. GAAP.

Previously identified material weaknesses in internal control over financial reporting

As part of the audit of our consolidated financial statements as of and for the years ended December 31, 2019 and 2018, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations.

The material weaknesses we identified were as follows:

- We did not maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting and controls knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely, completely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, amongst other things, our insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following material weakness.
- We did not design and maintain adequate controls over the preparation and review of certain account reconciliations and journal entries. Specifically, we did not design and maintain controls to ensure (i) appropriate segregation of duties in the preparation and review of account reconciliations and journal entries, and (ii) account reconciliations and journal entries were reviewed at the appropriate level of precision. This material weakness resulted in adjustments to prepaid expenses and accrued expenses which were identified and recorded as part of the audit of our consolidated financial statements as of and for the years ended December 31, 2019 and 2018.

Each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our consolidated financial statements that would not be prevented or detected, and accordingly, we determined these control deficiencies constitute material weaknesses.

Remediation Plan

We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses, including hiring additional finance and accounting personnel and initiating design and implementation of controls to enhance our internal controls over financial reporting including the establishment of formal accounting policies and procedures. In particular, we have hired a Chief Financial Officer and Vice President, Controller and retained as consultants certain finance and accounting personnel that were previously employed by Zafgen during the second quarter of 2020, to supplement our accounting and finance department during a transition period.

We believe the measures described above will remediate the control deficiencies we have identified and strengthen our internal control over financial reporting. We are committed to continuing to improve our internal control processes and will continue to review, optimize and enhance our financial reporting controls and procedures. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. The material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control Over Financial Reporting

Except as described above, there have been no changes in our internal control over financial reporting during the three months ended June 30, 2020 that 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

There have been no material changes to the risk factors described in our Current Report on Form 8-K filed with the SEC on June 2, 2020, as amended on June 26, 2020. The risks described in our Annual Report and such Current Report on Form 8-K are not the only risks facing our Company. Additional risk and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

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

There have been no sales of unregistered securities other than as previously disclosed by the Company in our Current Reports on Form 8-K as filed with the SEC, and as set forth below:

MTS Health Partners served as placement agent to us in connection with the Private Placement. As partial compensation for these services, we issued MTS Health Partners 35,260 shares of our common stock. The issuance of these securities were exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, in that the transaction was by an issuer not involving any public offering.

Our Registration Statement on Form S-3, filed with the SEC on June 26, 2020, registered the resale of 35,260 shares of common stock issued to MTS Health Partners.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On August 14, 2020, we entered into an Equity Distribution Agreement (the "Agreement") with Piper Sandler & Co. ("Piper Sandler"), 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 (the "ATM Shares") from time to time through Piper Sandler, as sales agent (the "Offering").

Under the Agreement, we 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. We pay Piper Sandler a commission equal to 3.0% of the gross proceeds of any ATM Shares sold through Piper Sandler under the Agreement and have agreed to reimburse the Piper Sandler for certain specified expenses. The Agreement contains customary representations, warranties and agreements by us, indemnification obligations of ourselves and Piper Sandler, other obligations of the parties and termination provisions. We have no obligation to sell any of the ATM Shares, and may at any time suspend offers under the Agreement.

The ATM Shares will be offered and sold pursuant to the Company's Registration Statement on Form S-3 filed by the Company on August 14, 2020 (the "Registration Statement") and the sales agreement prospectus that forms a part of such Registration Statement, following such time as the Registration Statement is declared effective by the Securities and Exchange Commission.

The description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which will be filed with the SEC as an exhibit to the Registration Statement.

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>
3.1	<u>Certificate of Amendment of Ninth Amended and Restated Certificate of Incorporation Of Zafgen, Inc. related to the Reverse Stock Split, dated May 28, 2020 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on June 2, 2020).</u>
3.2	<u>Certificate of Amendment of Ninth Amended and Restated Certificate of Incorporation Of Zafgen, Inc. related to the Name Change, dated May 28, 2020 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on June 2, 2020).</u>
4.1	<u>Form of Company Pre-funded Warrant to Purchase Common Stock by and among the Company and certain investors (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on June 2, 2020).</u>
10.1	<u>Securities Purchase Agreement, dated as of May 28, 2020, by and among the Company and the investors listed on the Schedule of Investors attached thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on June 2, 2020).</u>
10.2	<u>Registration Rights Agreement, dated as of June 1, 2020, by and among the Company and certain Investors (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on June 2, 2020).</u>
10.3	<u>Registration Rights Agreement, dated as of June 8, 2020, by and among the Company and certain Investors (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-3 filed on June 26, 2020).</u>
10.4	<u>Form of Indemnification Agreement between the Company and its directors (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on June 2, 2020).</u>
10.5	<u>Employment Agreement, dated June 1, 2020, by and between the Company and Michael Celano (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed on June 2, 2020).</u>
10.6*+	<u>License Agreement, by and between the Company and Wake Forest University Health Sciences, effective as of November 30, 2016.</u>
10.7*+	<u>Amendment 1 to License Agreement, by and between the Company and Wake Forest University Health Sciences, effective as of November 28, 2017.</u>
10.8*+	<u>Amendment 2 to License Agreement, by and between the Company and Wake Forest University Health Sciences, effective as of March 29, 2019.</u>
10.9*+	<u>License Agreement, by and between the Company and Indian University Research and Technology Corporation, effective as of November 30, 2016.</u>
10.10*+	<u>First Amendment to License Agreement, by and between the Company, the Trustee of Indiana University and Indiana University Research and Technology Corporation, effective as of August 16, 2019.</u>
10.11	<u>Notice of Substitute Option Grant between the Company and a certain Optionee (incorporated by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-8 filed on June 26, 2020).</u>

- 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: August 14, 2020

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

Date: August 14, 2020

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

LICENSE AGREEMENT

This License Agreement (the “Agreement”) is effective as of this 30th day of November, 2016 (the “Effective Date”) between Wake Forest University Health Sciences, having its principal offices at Medical Center Boulevard, Winston-Salem, North Carolina 27157 (“WFUHS”) and Chondrial Therapeutics IP Holdings, LLC (f/k/a Chondrial Therapeutics, LLC), having its principal offices at 4500 East 75th Street, Indianapolis, Indiana 46250 (“Chondrial”).

WHEREAS, WFUHS possesses certain patents and patent applications relating to non-viral delivery of compounds to mitochondria (WFU File 02-18); and

WHEREAS, Indiana University (“IU”), possesses a patent and patent application relating to certain testing methods related to Friedreich’s Ataxia; and

WHEREAS, IU had contractually appointed WFUHS as its sole exclusive agent for licensing IU’s interest in IU’s patent rights pursuant to a certain Inter-Institutional Agreement between WFUHS and IU dated January 20, 2009 (the “IIA”); and

WHEREAS, Chondrial, WFUHS and IU entered into an Option Agreement under the IIA dated February 14, 2014 with respect to certain of the patent rights; and

WHEREAS, Chondrial has exercised its option to obtain the license anticipated therein; and

WHEREAS, none of the patent rights involved in the anticipated license were jointly owned by WFUHS and IU; and

WHEREAS, Chondrial’s relationship with WFUHS and IU was going to be substantially different because there is no ongoing research related to the Licensed Patents occurring at WFUHS because the lead inventor left for IU in 2005; and

WHEREAS, WFUHS and IU determined that it was administratively easier to complete two distinct and separate license agreements rather than a single, three-party license agreement with the business terms of such distinct licenses being materially the same as the three-party license anticipated by the Option Agreement.

WHEREAS, WFUHS is willing to grant a license to Chondrial to the Licensed Patents (as defined below), subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises and covenants set forth herein, the parties hereto mutually agree as follows:

1. Definitions

For all purposes of this Agreement the following terms, whether used in the singular or plural, will have the meanings specified below:

“Affiliate” with respect to Chondrial means any corporation or entity that controls, is controlled by, or is under common control with Chondrial. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity; provided that if such other corporation or entity does not have voting stock or other ownership interests, a corporation or other entity shall be regarded as in control of such other corporation or entity if it possesses, directly or indirectly, (i) the power to direct or cause the direction of the management and policies of the corporation or other entity or (ii) the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the corporation or other entity.

“Affiliate” with respect to WFUHS means any entity or organization formally affiliated with the relevant institution.

“Biologics Act” means the Biologics Price Competition and Innovation Act, 42 U.S.C. § 262, or the equivalent law in any jurisdiction in which Chondrial commercializes or intends to commercialize Licensed Products.

“Commercially Reasonable Efforts” means the efforts and resources normally used by a party for a product, proposed product or technology owned by it or to which it has rights, which is of similar commercial potential at a similar stage in its development or product life, and having similar market potential, technical risk, and intellectual property protection. Commercially Reasonable Efforts shall be determined by taking into account the characteristics of the product, proposed product or technology, the technical risk and stage of research, development, or commercialization of the product, proposed product or technology, the cost-effectiveness of efforts or resources applied towards such product, proposed product or technology, the competitiveness of alternative third party products, proposed products or technologies that are in the relevant marketplace or for which data have been publicly presented or published, the proprietary position of the product, proposed product or technology, the regulatory and business environment, the likelihood of regulatory approval and product reimbursement, the actual or projected profitability of the product, proposed product or technology, the relative potential for product liability exposure, and all other relevant factors. Commercially Reasonable Efforts shall be determined on an individual product, proposed product or technology, basis, and country-by-country basis, and it is anticipated that the level of efforts and resources may change over time reflecting changes in the status of the product, proposed product or technology involved. In evaluating “commercial potential,” neither party shall discount or exclude the profit sharing, milestone or other payments payable under this Agreement to the other party/ies. “Effective Date” has the meaning given to it in the first sentence of this Agreement.

“Field” means the diagnosis, treatment and prevention of any disease that benefits from treatment with TAT-Frataxin, including without limitation Friedreich’s Ataxia.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

“IURTC Consideration” means the consideration Chondrial owes to Indiana University Research and Technology Corporation (IURTC) pursuant to the license agreement between IURTC and Chondrial with effective date November 30, 2016 that corresponds to the financial terms of this Agreement in Sections 3.1-3.4.

“Licensed Patents” means the Patents listed in Schedule A and all Patents (within the meaning of “Patents” as defined herein) related thereto owned or which WFUHS has the right to license, whether now issued or hereafter issuing.

“Licensed Product” means any product that, but for the license granted under this Agreement, would infringe a Valid Claim of a Licensed Patent.

“Net Sales” means Chondrial’s, its Affiliates’ and their respective Sublicensees’ gross receipts for any Licensed Product, less the sum of the following:

- [***];
- [***];
- [***];
- [***]; and
- [***].

(a) No deductions may be made for commissions paid to individuals for the sale of Licensed Products, whether they are independent sales agents or regularly employed by Chondrial, its Affiliates or Sublicensees, nor for any other cost incurred in the manufacture, marketing, sale, distribution, shipment, promotion, advertisement, exploitation or commercialization of Licensed Products.

(b) For all Licensed Products used by Chondrial, its Affiliates or Sublicensees, as premiums to promote, market, sell or lease product or processes other than Licensed Products, the Licensed Products in excess of the usual stand for such premiums and promotions will be deemed to have been sold at Chondrial’s then-current published third-party sales price for similar quantities.

(c) The transfer of any Licensed Product by Chondrial or one of its Affiliates to another Affiliate will not be considered a Net Sale, but the resale of such Licensed Product by any of the foregoing to third parties for commercial use shall be included in Net Sales.

For the avoidance of doubt, disposal of any Licensed Product for, or use of any Licensed Product in, free clinical trials, as free samples, or under compassionate use, patient assistance, named patient or test marketing programs or non-registrational studies or other similar programs or studies where Product is supplied or delivered without charge, shall not result in any Net Sales. No Licensed Product donated by Chondrial, its Affiliates or Sublicensees to non-profit institutions or government agencies for a non-commercial purpose shall result in any Net Sales. The use of any Licensed Product by Chondrial or one of its Affiliates or Sublicensees for research and development purposes shall similarly not result in any Net Sales.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

(d) If any Licensed Product is sold as part of a Combination Product (i.e., a product or a combination of products with at least two active ingredients, of which the manufacture, use or sale of at least one is not covered by the Licensed Patents), the Net Sales for such Licensed Product sold as part of a Combination Product shall be determined by multiplying the Net Sales of such Combination Product (replacing “Licensed Product” with “Combination Product” in the definition of Net Sales above), during the applicable period, by the fraction, $A/(A+B)$, where A is the average per unit sale price of such Licensed Product when sold separately as a standalone Licensed Product in finished form in the country in which the Combination Product is sold and B is the average per unit sale price of the other active ingredients contained in the Combination Product when sold separately as standalone products in finished form in the country in which the Combination Product is sold, in each case during the applicable period or, if sales of such standalone Licensed Product did not occur in such period, then in the most recent period in which arm’s length fair market sales of such Licensed Product, as applicable, occurred. If such average sale price cannot be determined for such Licensed Product or any of the other active ingredients, the Net Sales amount will be mutually agreed upon by the parties, based on the relative value contributed by each component, such agreement not to be unreasonably withheld, conditioned or delayed.

(e) The Parties acknowledge that, for purposes of calculating Net Sales under this License Agreement, Net Sales will be calculated in accordance with GAAP, defined as generally-accepted accounting principles in the United States, consistently applied.

“Non-patent Countries” means all countries or territories of the world other than Patent Countries.

“Patent” means any and all (a) U.S. or foreign patents, (b) U.S. or foreign patent applications, including, without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (c) U.S. or foreign patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates and regulatory exclusivities (including under 21 C.F.R. §§ 314 and 316) or equivalents thereof, and (d) other forms of government-issued right substantially similar to any of the foregoing.

“Patent Countries” means countries and territories in which there exists at least one Valid Claim of a Licensed Patent.

“Patenting Costs” means all reasonable costs for the preparation, filing, prosecution and maintenance of the Licensed Patents during the Term.

“Sublicense” means the grant by Chondrial or its Affiliate(s) or Sublicensees to a non-Affiliate third party (other than a Licensor or any of its Affiliates) of a sublicense under the Licensed Patents, either exclusive or non-exclusive, to practice some or all of the rights granted to Chondrial under this Agreement.

“Sublicense Consideration” has the meaning set forth in Section 3.3.

“Sublicensee” means any non-Affiliate third party to which Chondrial or its Affiliates or any of their respective Sublicensees grants a Sublicense.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

“Term” has the meaning given to it in Section 10.1. “U.S.” means the United States of America.

“Valid Claim” means a claim of a Patent that has not been held unpatentable, revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. If a claim of a pending patent application has not issued as a claim of an issued patent within five (5) years after the earliest priority date for such claim, such claim shall cease to be a Valid Claim unless and until such claim becomes an issued claim of an issued patent.

2. Grant of License

2.1 Subject to the terms and conditions of this Agreement, WFUHS hereby grants to Chondrial and its Affiliates, and Chondrial, on behalf of itself and its Affiliates, accepts from WFUHS for the Term an exclusive worldwide right and license under the Licensed Patents to research, develop, market and otherwise commercialize, make, have made, use, import, offer for sale and sell the Licensed Products, including Licensed Products and services for the treatment, diagnosis and prevention of disease in the Field, including the full right to sublicense through multiple tiers of Sublicensees any and all such rights and license.

2.2 In accordance with 35 U.S.C. §§ 200-212, 37 C.F.R. Part 401, and in the relevant government research contracts with WFUHS, the U.S. government retains certain rights and may impose certain requirements with respect to subject inventions as that term is defined therein. The rights granted in this Agreement are expressly made subject to these laws and regulations as they may be amended from time to time, and Chondrial agrees to comply and enable WFUHS to comply with all such laws and regulations, including without limitation to submit information requested by WFUHS’s reporting requirements in connection therewith. Chondrial represents and warrants that it, all Affiliates extended rights under Section 2.1, and all Sublicensees currently constitute a “small business firm” as defined in 13 CFR 121.802, and Chondrial will promptly notify Licensors of any change thereof that occurs during the term.

2.3 Notwithstanding the right and license granted in Section 2.1, Chondrial’s right and license is subject to WFUHS’s right to make, have made and use Licensed Products and practice the Licensed Patents for its own educational, academic, testing, clinical and research purposes, including the right to collaborate with other non-commercial entities for any non-commercial purposes. Without limiting the generality of the foregoing, neither WFUHS nor any of its Affiliates may participate directly or indirectly in producing any products which are sold to any person.

2.4 Chondrial agrees that any products constituting Licensed Products or any products produced through the use of Licensed Products will be manufactured substantially in the U.S. only to the extent required by 35 U.S.C. § 204, if such statute is applicable, unless a suitable waiver is obtained.

2.5 Except as expressly provided for in this Agreement, no license or other rights, either express or implied, are granted by WFUHS to Chondrial by the execution of this Agreement or the transfer of any materials or information hereunder.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

2.6 Chondrial will mark or have marked the packaging of all Licensed Products with the applicable Licensed Patents in a manner consistent with the laws and regulation then applicable in each such country, in the customary manner applied to drug products sold in such country.

3. License Fees, Royalties and other Consideration

3.1 Royalty. In partial consideration for the right and license granted under this Agreement, Chondrial will pay to WFUHS a royalty of (i) [***] of Net Sales for Licensed Products sold for ultimate use in Patent Countries or (ii) [***] of Net Sales for Licensed Products sold for ultimate use in Non-Patent Countries. For the sake of clarity, the royalties payable in this Article 3.1 apply to sales of Licensed Product by Chondrial or its Affiliates, Sublicensees or their respective Sublicensees. Non-sales based consideration such as upfront fees, milestones fees, etc. are addressed in Article 3.2 below.

3.2 Sublicense Fee. In partial consideration for the right and license granted under this Agreement, Chondrial will pay to WFUHS the following percentages of any and all Sublicense Consideration, excluding amounts received through royalties on Net Sales (which are covered by Section 3.1 above):

a) [***] during the period from the Effective Date through such time as Chondrial is obligated to pay WFUHS the milestone referred to in Section 3.4 (a); or

b) [***] during the period commencing upon the occurrence of the event referred to in Section 3.2 (a) above through such time as Chondrial is obligated to pay WFUHS the milestone referred to in Section 3.4 (b); or

c) [***] during the period commencing upon the occurrence of the event referred to in Section 3.2 (b) above and continuing thereafter during the Term.

3.3 For purposes of this Agreement, “Sublicense Consideration” means [***]. For the removal of doubt, Sublicense Consideration excludes [***]. For the further removal of doubt, to the extent a Sublicense agreement includes the grant of rights unrelated to the rights to the Licensed Patents, “Sublicense Consideration” shall only include a portion of amounts paid by a Sublicensee equal to the proportional value of the Licensed Patents relative to the value of the other unrelated rights granted to such Sublicensee in such Sublicense agreement.

3.4 Milestones. In partial consideration for the right and license granted under this Agreement, Chondrial will pay to WFUHS the following amounts upon the achievement of the following events:

a) Enrollment of the first patient in the first Phase I (or its non-U.S. equivalent) clinical trial of a Licensed Product: [***];

b) Enrollment of the first patient in the first Phase II (or its non-U.S. equivalent) clinical trial of a Licensed Product: [***];

c) [***]: [***];

d) [***]: [***];

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

3.4.1 The events listed in this Section 3.4(a) – (d) are intended to be sequential and reflect the presumed path that a Licensed Product will take through the regulatory approval process. If any of these events does not occur for any reason, the fee due upon that skipped event(s) will be due upon the achievement of the subsequent event (and in no event later than the first commercial sale of the first Licensed Product).

3.5 In the event that Chondrial is required to pay IURTC Consideration, then Chondrial may deduct twenty percent (20%) of such IURTC Consideration, on a dollar-for-dollar basis, from the consideration due to WFUHS under Sections 3.1-3.4.

3.6 Equity. In partial consideration for the rights granted under the option agreement among Chondrial, IURTC, and WFUHS dated February 14, 2014, Chondrial will issue to WFUHS 14,622 Common Units of Chondrial Therapeutics Holdings, LLC (“Chondrial Holdings”). In connection with the issuance of the Common Units to WFUHS, WFUHS will be required to execute an Investors’ Rights Agreement, Right of First Refusal and Co-Sale Agreement, and Amended and Restated Limited Liability Company Agreement, substantially in the forms attached hereto as Exhibits A-C, respectively, which will be executed concurrently with the execution of this Agreement.

4. Sublicenses

4.1 Upon termination of this Agreement, Chondrial will promptly notify its Affiliates extended rights under Section 2.1 and Sublicensees of such termination. Any rights previously granted by Chondrial under Section 2.1 will not be automatically terminated, provided, however, that any Sublicensee who desires to continue its Sublicense advises WFUHS in writing within thirty (30) days following the effective date of termination of this Agreement of its desire to continue the Sublicense, and includes a statement demonstrating its solvency and agreement to be bound to WFUHS on the same terms and conditions, including without limitation financial terms, as Sublicensee was bound to Chondrial under the Sublicense. Failure of a Sublicensee to timely provide such notice will automatically result in the termination of the Sublicense and all rights granted thereunder or hereunder. Upon receipt of such Sublicensee notice, WFUHS will have a period of thirty (30) days to provide its written consent for the continuation of the Sublicense, such consent will not be unreasonably withheld.

4.2 All terms and conditions applicable to Sublicensee hereunder will also apply to Sublicensee’s Sublicense.

4.3 All Sublicenses will contain appropriate provisions in accordance with the obligations of Chondrial to, and the rights of, WFUHS under this Agreement. Each Sublicense will be consistent with the terms and conditions of this Agreement.

4.4 Chondrial will provide notice to Licensors of any Sublicense granted that may be reasonably expected to result in payments to WFUHS under Section 3 hereof, and will provide a copy of all such Sublicenses within thirty (30) days after execution. Chondrial will promptly provide Licensors with true and accurate copies of all reports received from a Sublicensee related to the calculation of any consideration payable to WFUHS hereunder.

4.5 Chondrial agrees to use Commercially Reasonable Efforts to cause Sublicensees to perform their obligations as Sublicensees. To the extent Chondrial becomes aware of an act or omission by a Sublicensee that would be a breach of this Agreement if imputed to Chondrial and fails to use Commercially Reasonable Efforts to cause Sublicensee to cure or mitigate such breach, then the act or omission will be deemed to be a breach by Chondrial of this Agreement.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

4.6 No such sublicense or attempt to obtain a sublicensee shall relieve Chondrial of its obligations under Section 5 hereof to exercise its Commercially Reasonable Efforts, directly or through a sublicense, to discover, develop and market Products, nor relieve Chondrial of its obligations to pay WFUHS any and all license fees, royalties and other payments due under the Agreement, including but not limited to under Sections 3 of the Agreement. Such sublicenses may be further sublicensed to multiple tiers of sublicensees. For clarity, each such sublicense is hereinafter referred to as a "Sublicense," and each such Third Party sublicensee and its sublicensees as a "Sublicensee."

5. Diligence

5.1 Chondrial will use Commercially Reasonable Efforts to bring the Licensed Products to market through exploitation of the Licensed Patents and commercialization of the Licensed Products.

5.2 Without limiting the generality of the diligence provisions of Section 5.1 above, Chondrial will achieve (either itself or through its Affiliates and/or its Sublicensees) the following milestones by the following dates ("Milestones"):

Chondrial, its Affiliates and/or Sublicensees will have at least two (2) full-time equivalent personnel working on the development, manufacturing and marketing of the Licensed Products within the twelve (12) month period from the Effective Date and each subsequent year thereafter;

Enrollment of the first patient in the first Phase I (or its non-U.S. equivalent) clinical trial of a Licensed Product within thirty (30) months from the Effective Date;

Enrollment of the first patient in the first Phase II (or its non-U.S. equivalent) clinical trial of a Licensed Product within sixty (60) months from the Effective Date;

5.2.1 Chondrial will provide to Licensors (at the time of the next due report under Section 8) written notice of the achievement of each Milestone in this Section 5.2.

5.3 Chondrial will use Commercially Reasonable Efforts to have the Licensed Products cleared for marketing in those countries in which Chondrial, in its sole discretion, intends to sell Licensed Products by the responsible governmental agencies requiring such clearance. To accomplish such clearances at the earliest possible date, Chondrial will file, according to the usual practice of companies similarly situated to Chondrial, any necessary data with such governmental agencies. For clarity, the development and commercialization of the Licensed Products outside of the U.S. is at Chondrial's sole discretion.

5.4 As a new business entity, Chondrial's ability to diligently and effectively commercialize the Licensed Products requires it to raise sufficient capital to do so. Chondrial shall notify WFUHS in writing as it meets each capital milestone specified hereinbelow. Should Chondrial fail to raise the capital according to the schedule hereinbelow and neither take the actions set forth in the following sentence nor receive a sixty (60) day extension as provided for in this Section 5.4, WFUHS shall, at its sole option, have the right to terminate this Agreement pursuant to Section 9.2 of this Agreement. In the event it appears to Chondrial that it will not be able to achieve one or more of these capital milestones, it may request a sixty (60) day extension to achieve the applicable milestone, which extension will not be unreasonably denied by WFUHS, provided Chondrial can demonstrate, to WFUHS' reasonable satisfaction, a reasonable diligence in pursuing such milestone. The capital milestones are as follows:

- a) Raise One Million Dollars (\$1,000,000 U.S.) by December 31, 2016;

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

- b) Raise a cumulative Two Million Dollars (\$2,000,000 U.S.), by December 31, 2017; and
- c) Raise a cumulative Four Million Dollars (\$4,000,000 U.S.), by December 31, 2018.

6. Disclaimer of Warranties and Representations

6.1 Except as set forth in this Agreement, all property, whether tangible or intangible, which may be delivered hereunder, will be delivered on an “as is, where is” basis without any express or implied representation or warranty.

6.2 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, WFUHS MAKES NO REPRESENTATIONS AND EXTENDS NOWARRANTIES WHATSOEVER AND HEREBY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, IMPLIED REPRESENTATIONS AND WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY IMPLIED REPRESENTATIONS AND WARRANTIES ARISING FROM ANY COURSE OF DEALING, USAGE OR TRADE PRACTICE. WFUHS ASSUMES NO RESPONSIBILITY WITH RESPECT TO THE EXPLOITATION OR COMMERCIALIZATION OF THE LICENSED PATENTS OR THE MANUFACTURE, USE, SALE, LEASE OR DISTRIBUTION OF ANY METHODS, PROCESSES, APPARATUS, DEVICES, SYSTEMS, PRODUCTS, ARTICLES AND APPLIANCES DERIVED FROM OR USING THE LICENSED PRODUCTS BY CHONDRIAL.

6.3 WFUHS WILL NOT BE LIABLE TO CHONDRIAL FOR LOSS OF PROFITS, LOSS OF USE OR ANY OTHER DIRECT, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES.

7. Records, Reports and Payments

7.1 Chondrial will keep and maintain and will require any and all of its Affiliates, and their respective Sublicensees to keep and maintain complete, accurate and correct records and books relating to the sale, lease, use or disposition of the Licensed Products and any and all payments or consideration associated with this Agreement for at least three (3) years following the end of the calendar year to which such records and books pertain.

7.2 Chondrial will provide to WFUHS written reports annually from the Effective Date of this Agreement until the first commercial sale of a Licensed Product, and thereafter for each calendar quarter as of January 1, April 1, July 1 and October 1 of each calendar year during the remaining Term of this Agreement, the written reports to be provided within forty five (45) days of the end of each such period, setting forth the following information:

- a) Milestones achieved, Sublicenses signed, Affiliates developed;
- b) accounting for any and all Licensed Products sold, distributed, transferred, used or leased;
- c) gross receipts of Licensed Products;
- d) any applicable deductions, allowances and charges as provided in the definition of Net Sales;
- e) total Net Sales; and
- f) total royalties, sharing of consideration received from Sublicensees and any other payments or consideration under this Agreement then due.

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7.2.1 Chondrial will give to WFUHS with each such report and on the date specified above the full amount of any and all payments due. Following the date of first commercial sale of a Licensed Product, if no sales or leases of the Licensed Products were made during any calendar quarter, Chondrial will provide to WFUHS a statement to that effect. Prior to the first commercial sale of a Licensed Product, Chondrial will annually provide WFUHS with a brief summary of progress made by Chondrial, its Affiliates and their respective Sublicensees towards the commercialization of the Licensed Products.

7.3 The books and records of account kept by Chondrial pursuant to Section 7.1 above shall be made available upon reasonable notice, during normal business hours for examination by one or more independent auditors of WFUHS's choosing, reasonably acceptable to Chondrial, who will be permitted to enter upon the premises of Chondrial to examine such books and records to verify all amounts payable to WFUHS under this Agreement and make and retain copies of any and all parts of said books and records of account, including invoices that are relevant to any report required to be rendered by Chondrial; provided, however, that such examination will occur no more than once per calendar year and that such auditor(s) will enter into confidentiality agreements reasonably acceptable to Chondrial. Said copies will be provided to the auditor without cost to Chondrial. Any amount found to have been owed but not paid will be paid promptly to WFUHS with simple interest at an annual rate equal to [***] above the prime rate published in the Eastern edition of The Wall Street Journal at the beginning of the period of arrearage. Any amount found to have been paid but not owed will be credited against future payments to WFUHS. In the event any such audit shows that Chondrial has underpaid its royalty obligation hereunder by [***] or more, during any calendar year, Chondrial will reimburse WFUHS for WFUHS's reasonable out-of-pocket expenses for such audit.

7.4 Royalty or other payments will be paid in U.S. Dollars to WFUHS in Winston-Salem, North Carolina, or at such other place as WFUHS may reasonably designate consistent with the laws and regulations controlling in any foreign country. If any royalties hereunder are based on sales converted from foreign currency, such conversion will be made by using the exchange rate published in the U.S. edition of the Wall Street Journal on the last day of the calendar quarter period to which such royalty payments relate.

7.5 If laws or regulations require that any other taxes be withheld by Chondrial from any payments hereunder, the parties shall determine how the appropriate tax payment can be made and take appropriate steps to ensure that such payments be made, it being understood that Chondrial will use its Commercially Reasonable Efforts to cooperate with WFUHS to minimize any such amounts to be withheld.

8. Patent Prosecution

8.1 WFUHS will manage the filing and prosecution of the U.S. and foreign patent applications and maintenance of all U.S. and foreign patents comprising the Licensed Patents as reasonably counseled by Chondrial. Chondrial acknowledges that the Licensed Patents represent a mature patent portfolio without any patent applications in active prosecution.

8.2 As of the Effective Date, WFUHS has expended \$88,754.50 on the Licensed Patents. Upon execution of this Agreement, Chondrial will reimburse \$30,000 of such historic patent expenses. Upon the one-year anniversary of this Agreement, Chondrial will reimburse an additional \$30,000 in such historic patent expenses. Upon the two-year anniversary of this Agreement, Chondrial will reimburse the remaining \$28,754.50 in historic patent expenses.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

8.2.1 Accelerated Reimbursement Upon Successful Financing: Notwithstanding Section 8.2 above, if Chondrial completes an venture capital financing of five million dollars (\$5,000,000 U.S.) either in a single financing event or cumulative of multiple rounds of capital fund-raising, Chondrial will promptly reimburse WFUHS for any remainder of the \$88,754.50 historic patent expenses above.

8.3 Within sixty (60) days of presentation of itemized statements to Chondrial, Chondrial will reimburse WFUHS for all Patenting Costs. Any amounts due under this Section 8.3 and remaining unpaid after ninety (90) days will accrue simple interest at an annual rate equal to [***] above the prime rate published in the Eastern edition of The Wall Street Journal at the beginning of the period of arrearage.

8.4 Chondrial shall have the right to approve the patent counsel chosen by WFUHS, which approval shall not be unreasonably withheld. WFUHS shall provide at least thirty (30) days' prior notice to Chondrial of all actions regarding the filing, prosecution and maintenance of any of the U.S. or foreign patent applications or patents within the Licensed Patents. Chondrial shall have the right to review all correspondence and documentation (including without limitation patent applications) with respect to all such patent applications or patents within the Licensed Patents, and to make comments thereon, before submission of any such correspondence or documentation. Chondrial shall effect the foregoing in a timely manner. WFUHS will in good faith take any Chondrial comments into consideration.

8.5 WFUHS shall provide annual written reports to Chondrial upon request to inform Chondrial of projected costs associated with the filing, prosecution or maintenance of any U.S. or foreign patent applications or patents within the Licensed Patents. If Chondrial determines that any filing, prosecution or maintenance cost is not justified, it will advise WFUHS in writing within thirty (30) days from receipt of the written report and the parties will discuss the matter in good faith, taking into consideration and giving significant weight to Chondrial's marketing and commercialization plans.

9. Termination

9.1 Unless sooner canceled or terminated as herein provided, this Agreement will continue until the last to expire Valid Claim within the Licensed Patents (including any period of regulatory exclusivity thereof), unless earlier terminated as set forth herein (the "Term"), subject to the royalty rates on a country-by-country basis as set forth in Section 3.

9.2 If either Chondrial or its Affiliate commits a material breach of any covenant or obligation set forth herein, WFUHS will have the right, in addition to all other remedies available, to terminate this Agreement by giving Chondrial sixty (60) days prior written notice of such termination, provided, however, that if Chondrial will have rectified such default or breach within such 60-day period, this Agreement will remain in effect and in force as if no default or breach had occurred.

WFUHS may terminate this Agreement under Section 9.2 if Chondrial at any time (a) ceases to carry Director's and Officer's insurance with coverage levels appropriate for Chondrial's then-current stage of development or (b) ceases to have at least one employee or consultant who is devoting roughly a half-time effort (i.e., 20 hours/week) to the affairs of Chondrial.

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9.3 To the extent permitted by applicable law, if Chondrial or its Affiliates become bankrupt or insolvent, or file a petition in bankruptcy, or if the business of Chondrial or its Affiliates is placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of Chondrial or its Affiliates or otherwise, the Agreement and any and all rights granted thereunder will automatically terminate without any notice whatsoever to Chondrial.

9.4 Chondrial will have the right to terminate this Agreement with or without cause upon thirty (30) days' written notice to WFUHS.

9.5 If at any time Chondrial or its Affiliates directly or indirectly disputes or assists any third party to dispute the validity of any patent comprising the Licensed Patents, to the extent permitted by applicable law: (i) WFUHS will be entitled thereafter to terminate immediately all or any portion of the licenses granted hereunder by written notice thereof to Chondrial and (ii) the royalties payable to WFUHS under Section 3 hereunder will be trebled during the pendency of such action disputing the validity of the Licensed Patents.

9.6 Upon expiration or termination of this Agreement for any reason, (i) nothing herein will be construed to release either party from any obligation accrued prior to the effective date of such termination and (ii) all rights granted hereunder will immediately revert to WFUHS.

10. Infringement

10.1 Each party will promptly inform the other in writing of any alleged infringement by a third party or other unauthorized party of any of the patents comprising the Licensed Patents, and provide such other party with any available evidence of infringement. Chondrial will not settle or compromise any claim or action, including, without limitation, any declaratory judgment action alleging invalidity or noninfringement of any of the Licensed Patents, in a manner that imposes any restrictions, limitations, responsibilities or obligations on WFUHS without WFUHS's express written consent, which shall not be unreasonably withheld, it being understood that such decision shall take into account Chondrial's overall marketing and commercialization plan to the extent communicated to Licensors.

10.2 During the Term, Chondrial will have the first right, but not the obligation, to prosecute at its own expense any such infringements of the Licensed Patents and, in furtherance of such prosecution, Chondrial may join WFUHS as a party plaintiff in any such suit, without expense to WFUHS. Similarly, during the Term, Chondrial will have the right to defend at its own expense any declaratory judgment action alleging invalidity or non-infringement of any of the Licensed Patents, and, in furtherance thereof, Chondrial may join WFUHS as a party in any such suit, without expense to WFUHS. The total cost of any such action commenced or defended solely by Chondrial will be borne by Chondrial. Any recovery of damages by Chondrial as a result of such action shall be applied first in satisfaction of any reasonable unreimbursed expenses and attorneys' fees of Chondrial relating to the action. The balance remaining from any such recovery shall be distributed to Chondrial, provided that Chondrial will pay to WFUHS such royalties as would otherwise be applicable under Section 3.1 hereof for that portion of Chondrial's recovery attributable to lost Net Sales.

10.3 If, within One Hundred Eighty (180) days after having been notified in writing of any alleged infringement, Chondrial has been unsuccessful in persuading the alleged infringer to desist, or has not brought, or otherwise is not diligently prosecuting, an infringement action, or if Chondrial notifies WFUHS at any time prior thereto of its intention not to bring suit against any alleged infringer, then, and in those events only, WFUHS will have the right, but not the obligation, to prosecute at its own expense any infringement of the Licensed Patents. Settlement, consent judgment or other voluntary final disposition of the suit may be entered into by WFUHS without the consent of Chondrial, provided, however that WFUHS will not settle or compromise any claim or action, including without limitation any declaratory judgment action alleging invalidity or noninfringement of any of the Licensed Patents, in a manner that imposes any monetary obligations on Chondrial, without Chondrial's express written consent. The total cost of any such infringement action commenced or defended solely by WFUHS will be borne by WFUHS and WFUHS will keep any recovery or damages, for past infringement or otherwise, derived therefrom.

10.4 Without limiting the effect of any other provision hereof, in the event an action for infringement or any declaratory judgment action alleging invalidity or noninfringement of any of the Licensed Patents, is brought arising from the practice of the Licensed Patents, Chondrial (and/or its relevant Affiliate or Sublicensee) will have the right to defend such action and will be solely responsible for all attorneys' fees, costs of defense, and liability arising out of that action, and Chondrial will keep any recovery and damages derived therefrom or from any counterclaims asserted therein.

10.5 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the Licensed Patents is brought, and Chondrial (and/or its relevant Affiliate or Sublicensee) declines to defend the same or otherwise is not diligently defending such action in the reasonable opinion of WFUHS counsel, then, and in those events only, WFUHS, at its option, will have the right to intervene and take over the sole defense of the action at its own expense and whereupon WFUHS will keep any recovery and damages derived therefrom or from any counterclaims asserted therein.

10.6 In any infringement suit brought or declaratory judgment action defended by either party to protect any of the Licensed Patents pursuant to this Agreement, the other party will, at the request and expense of the party controlling such suit and at such party's expense, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens and the like.

10.7 Without limiting the foregoing provisions regarding infringement in Sections 10.1-10.6, in the event any party receives any notice during the Term relating to the development of or application for a "biosimilar" for which a Licensed Product is the "reference product" (within the meaning of the Biologics Act), it shall promptly notify the other parties and they shall conduct good faith negotiations with respect to any and all responses thereto, including without limitation the sharing of information regarding the Licensed Patents and/or the Licensed Products with the applicant for such biosimilar.

11. Indemnification and Insurance

11.1 Chondrial and its Affiliates will, at all times during the Term and thereafter, indemnify, hold harmless and defend WFUHS and its trustees, officers, directors, employees, agents, students and affiliates (collectively “WFUHS Indemnitees”) from and against all claims, losses, damages, and liabilities of whatsoever kind or nature relating to the operations performed by Chondrial or its Affiliates pursuant to this Agreement, as well as all costs and expenses, including legal expenses and reasonable attorneys’ fees (“Losses”), to which WFUHS Indemnitees may become subject as a result of any third party claim, demand, action or other proceeding arising or that may arise at any time out of or in connection with this Agreement or with any activity of Chondrial, its Affiliates, and their respective Sublicensees involving the Licensed Products or the Licensed Patents, including without limitation the manufacture, use, sale, lease, commercialization, licensing or distribution of Licensed Products or any system, method, process, apparatus, device, product, article or appliance derived from or using the Licensed Products or the Licensed Patents, in each case except to the extent that any such Losses arise out of the breach of this Agreement, negligence, recklessness, bad faith or intentional wrongful acts or omissions committed by the WFUHS Indemnitee who is the subject of such action.

11.2 WFUHS will not be liable, including without limitation to Chondrial, its Affiliates, its Sublicensees and their respective affiliates, successors, assigns, independent contractors and agents, or to any third party regarding any claim arising from or relating to the exercise of any right granted, including without limitation Chondrial’s use of the Licensed Patents; or from the manufacture, use, or importation of products; or for any claim for loss of profits or loss or interruption of business; in each case except to the extent that any such claim arises out of the breach of this Agreement, negligence, recklessness, bad faith or intentional wrongful acts or omissions committed by a Licensor which is the subject of such claim.

11.3 Chondrial, its Affiliates and their respective sublicensees will carry liability insurance at their expense, to assure its obligations under Section 11.1 of this Agreement. Chondrial will include satisfactory evidence of such insurance coverage with each quarterly report required by Section 7 of this Agreement. Commencing with the first commercial sale of a Licensed Product (the “Product Period”), such insurance will be in include policies for Commercial General Liability, including but not limited to, Products, Contractual, Fire, Legal and Personal Injury and Products liability in amounts customary

in the industry and sufficient to cover its liabilities and obligations hereunder, taking into account the actual stage of product development and commercialization of any Licensed Product.

Prior to the Product Period, Chondrial, its Affiliates and any of their respective sublicensees will carry workers’ compensation, automobile and general liability insurance at their own expense, adequate to assure its obligations to WFUHS under Section 11.1 of this Agreement.

Chondrial, its Affiliates and their respective sublicensees will (i) provide satisfactory evidence of adequate insurance coverage to WFUHS upon the request of WFUHS and (ii) have WFUHS named as an additional insured on all such liability coverage policies.

12. Confidentiality

12.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, each party agrees that, during the Term and for five (5) years thereafter, such party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any information furnished to it by the other party pursuant to this Agreement that is marked "confidential" or which is or should reasonably be known to be confidential ("Confidential Information"). Such party (the "Receiving Party") may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party will promptly notify the other party upon discovery of any unauthorized use or disclosure of the Confidential Information. In appreciation of WFUHS's status as an academic institution, Chondrial will take reasonable steps to limit the amount of Chondrial's Confidential Information that is shared with WFUHS to that which is required by this Agreement or that which WFUHS needs or wants in order to enhance WFUHS's performance under this Agreement.

12.2 Exceptions. Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available; (b) is known by the Receiving Party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party by a third party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party without the use of Confidential Information of the other party.

12.3 Authorized Disclosure. Each party may disclose Confidential Information of the other party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

- a) filing or prosecuting patents as permitted by this Agreement;
- b) prosecuting or defending litigation as permitted by this Agreement;
- c) complying with applicable court orders or governmental regulations;
- d) in the case of Chondrial, disclosure to a party's Affiliates, provided that Confidential Information so disclosed shall remain subject to this Section 13; and
- e) in the case of Chondrial, disclosure to third parties in connection with due diligence or similar investigations by such third parties, and disclosure to potential third party investors in confidential financing documents, provided, in each case, that any such third party agrees to be bound by reasonable obligations of confidentiality and non-use.
- f) IURTC may report consideration received under this Agreement and Chondrial's progress under Section 8 to IU and the Inventors and to the U.S. government under Section 2.2.
- g) in connection with litigation.

Notwithstanding the foregoing, if a party is required to make a disclosure of the other party's Confidential Information pursuant to Section 13.3(b) or (c) it will, except where impracticable, give reasonable advance notice to the other party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. The parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by the parties with the Securities and Exchange Commission or as otherwise required by law.

13. Assignment

13.1 Chondrial may assign or otherwise transfer this Agreement and the license granted hereby and the rights acquired by it hereunder, whether voluntarily, by merger, operation of law or otherwise, only in whole and not in part, without any consent of or notice to WFUHS, to an Affiliate or to the assignee or transferee of Chondrial's or its Affiliate's business or of that part of Chondrial's or its Affiliate's business to which this Agreement directly relates; provided, however, that such Affiliate, (i) assignee or transferee agrees in writing to be bound by the terms and conditions of this Agreement, and (ii) is not materially insolvent.

13.2 Chondrial shall provide WFUHS with prior written notification of any potential assignee, and upon such notification WFUHS shall have ten (10) business days to notify Chondrial of any good faith objection to the assignment to such potential assignee as being reasonably likely to materially harm the reputation of WFUHS, and provide a detailed written statement describing the bases underlying the objection. Upon a timely objection under Section 13.2, Chondrial may not assign or otherwise transfer this Agreement to such potential assignee without prior written consent of WFUHS. Failure of WFUHS to object to the potential assignee within the time period stated above will be deemed a waiver of any objection under Section 13.1(ii).

14. Non-Use of Names

14.1 Neither party will use the names of the other or of the employees of such other party, nor any adaptation thereof, in any advertising, promotional or sales activities without prior written consent from such other party in each separate case, except that Chondrial may state that it is licensed by WFUHS under one or more of the patents and patent applications within the Licensed Patents and. Each party shall hold the specific financial terms of this Agreement (including without limitation royalty rates and measurement mechanisms and the payments called for upon milestone events) in confidence and will not disclose the same publicly without the prior consent of the other party, which consent shall not be unreasonably withheld or delayed. However, nothing herein will prohibit any public disclosure that is required by any applicable law or regulation or by any competent governmental authority; provided, that the party subject to such disclosure requirement will provide reasonable prior notice to the other party or in connection with corporate or financial transactions on the part of Chondrial.

14.2 Licensors and Chondrial agree to issue a mutually acceptable press release shortly after the Effective Date.

15. Export Controls

15.1 It is understood that WFUHS is subject to U.S. laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities that may require a license from the applicable agency of the U.S. government or may require written assurances by Chondrial that Chondrial will not export data or commodities to certain foreign countries without prior approval of such agency. WFUHS does not represent that a license is not required, or that, if required, such a license will be given.

16. Payments, Notices and Other Communications

16.1 Any payment, notice, or other communication pursuant to this Agreement will be sufficiently made or given on the date of mailing if sent to such party by email, overnight courier (e.g. Federal Express) or certified first class mail, postage prepaid, addressed to it at its address below or as it will designate by written notice given to the other party:

WFUHS: ATTN: Vice President
 Center for Technology Innovation and Commercialization
 Wake Forest Innovations
 391 Technology Way, Suite 199
 Winston-Salem, NC 27101
 Phone: 336-716-3729 (not for official communications)
 Fax: 336-777-3259 (not for official communications)
 Email: otc@wakehealth.edu (not for official communications)

Chondrial: Chondrial Therapeutics IP Holdings, LLC
 4500 E. 75TH Street
 Indianapolis, IN 46250
 Attention: Steven R. Plump
 Phone: (317) 578-1596
 Email: info@chondrialtherapeutics.com

17. Miscellaneous Provisions

17.1 The parties hereto acknowledge that this Agreement sets forth the entire agreement and understanding of the parties hereto as to the subject matter hereof, and will not be subject to any change or modification except by the execution of a written instrument signed by the parties hereto.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

17.2 The provisions of this Agreement are severable, and in the event that any provision of this Agreement will be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability will not in any way affect the validity or enforceability of the remaining provisions hereof.

17.3 The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

17.4 This Agreement will be binding and inure to the benefit of the parties hereto and their respective affiliates, and permitted successors and assigns.

17.5 The representations, warranties, covenants, and undertakings contained in this Agreement are for the sole benefit of the parties hereto and their permitted successors and assigns and such representations, warranties, covenants, and undertakings will not be construed as conferring any rights on any other party.

17.6 Nothing contained in this Agreement will be deemed to place the parties hereto in a partnership, joint venture or agency relationship and neither party will have the right or authority to obligate or bind the other party in any manner.

17.7 This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which taken together will constitute one and the same instrument.

17.8 Each party has consulted its own counsel during the drafting of this Agreement and agrees that in the event of a dispute the language of this Agreement will not be deemed to have been drafted by either individual party.

17.9 This Agreement shall be governed by the laws in effect in the State of North Carolina. Any claim or dispute brought regarding the terms or performance of this Agreement will be adjudicated in the state or federal Courts of North Carolina. Each party agrees to be subject to the jurisdiction of the relevant court in order to effect the foregoing.

17.10 As of the Effective Date, Chondrial represents and warrants that it is a small entity as defined in 37 C.F.R. 1.27, and it will promptly notify Licensors of any change to its entity status through acquisition, addition of employees, sublicensing this Agreement, or any other mechanism.

17.11 The provisions of Sections 1 (Definitions), 4 (Sublicenses), 6 (Disclaimer), 10 (Infringement), 11 (Indemnification), 12 (Confidentiality), 15 (Export Controls), 16 (Payments, Notices, Communication) and 17 (Miscellaneous, as relevant) survive the termination or expiration of this Agreement.

17.12 All rights and licenses granted under or pursuant to this Agreement and any Sublicense are licenses of rights to "intellectual property" as defined in Section 365(n) of Title 11 of the United States Code ("Title 11"). Each Party agrees that the other Party, as licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under Title 11. Each Party agrees during the Term, to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property.

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IN WITNESS WHEREOF, the parties hereto have hereunto set their hands and seals and duly executed this Agreement as of the day and year first set forth above.

Wake Forest University Health Sciences

By: /s/ Jeffrey P. Brennan

Name: Jeffrey Brennan

Title: Vice President, Center for Technology Innovation and Communications

Date: _____

Chondrial Therapeutics IP Holdings, LLC

By: Chondrial Therapeutics Holdings, LLC, its sole member

By: /s/ Steven R. Plump

Name: Steven Plump

Title: Authorized Representative

Date: 11-30-2016

EXHIBIT A
CHONDRIAL THERAPEUTICS HOLDINGS, LLC INVESTORS' RIGHTS AGREEMENT
[SEE ATTACHED]

[Exhibit A to License Agreement]

EXHIBIT B
CHONDRIAL THERAPEUTICS HOLDINGS, LLC RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT
[SEE ATTACHED]

[Exhibit B to License Agreement]

EXHIBIT C
CHONDRIAL THERAPEUTICS HOLDINGS, LLC
AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT
[SEE ATTACHED]

[Exhibit C to License Agreement]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

SCHEDULE A

LICENSED PATENTS

1. [***].
2. [***].
3. [***].

[Schedule A to License Agreement]



150 Monument Road, Suite 207
Bala Cynwyd, PA 19004

November 28, 2017

Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, North Carolina 27157
Attention: Chief Innovation Officer

Ladies and Gentlemen:

Reference is made to:

(i) that certain License Agreement dated as of November 30, 2016 (the “Agreement”), by and among Chondrial Therapeutics IP Holdings, LLC (f/k/a Chondrial Therapeutics, LLC) and Wake Forest University Health Sciences.

By their signatures below and for good and valuable consideration, the parties hereby acknowledge and agree as follows:

1. Chondrial Party.

Chondrial Therapeutics IP Holdings, LLC (f/k/a Chondrial Therapeutics, LLC), having its principal offices at 4500 East 75th Street, Indianapolis, Indiana 46250 was listed in error as a party to the Agreement. The proper and full name and address of the Chondrial entity that is a party to the Agreement is Chondrial Therapeutics IP, LLC, a Delaware Limited Liability Company, having its principal offices at 150 Monument Road, Suite 207, Bala Cynwyd, PA 19004.

Accordingly, the Agreement is hereby amended as of the date hereof to replace “Chondrial Therapeutics IP Holdings, LLC (f/k/a Chondrial Therapeutics, LLC), having its principal offices at 4500 East 75th Street, Indianapolis, Indiana 46250” with “Chondrial Therapeutics IP, LLC, a Delaware Limited Liability Company having its principal offices at 150 Monument Road, Suite 207, Bala Cynwyd, PA 19004.”

2. Effect.

Except as amended hereby, the Agreement shall remain in full force and effect.

3. No Waiver.

This Letter Amendment is effective only in the specific instance and for the specific purpose for which it is executed and shall not be considered a waiver or agreement to amend as to any provision of the Agreement in the future.

4. Counterparts.

This Letter Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

Very truly yours,

Chondrial Therapeutics IP, LLC

By: /s/ Jennifer S. Johansson

Name: Jennifer S. Johansson

Title: Vice President of Regulatory Affairs and Counsel

ACCEPTED AND AGREED TO
as of the date first above written:

Wake Forest University Health Sciences

By: /s/ Eric Tomlinson

Name: Eric Tomlinson, D.Sc., PhD

Title: Chief Innovation Officer



150 Monument Road, Suite 207
Bala Cynwyd, PA 19004

March 29, 2019

Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, North Carolina 27157
Attention: Chief Innovation Officer

Dear Sir/Madam:

Reference is made to that certain License Agreement dated as of November 30, 2016 (the "**Agreement**") and an Amendment to such License Agreement dated November 28, 2017 (the "**Amendment No. 1**"), by and among Chondrial Therapeutics IP, LLC and Wake Forest University Health Sciences.

By their signatures below and for good and valuable consideration, the parties hereby acknowledge and agree as follows:

1. Diligence-Section 5.2 Amendment.

The parties desire, effective as of the date hereof, to amend Section 5.2 of the Agreement by replacing paragraphs 3 and 4 with the following language:

[***].

[***].

2. Effect.

Except as amended hereby, the Agreement and Amendment No. 1 shall remain in full force and effect.

3. No Waiver.

This Letter Amendment No. 2 is effective only in the specific instance and for the specific purpose for which it is executed and shall not be considered a waiver or agreement to amend as to any provision of the Agreement and/or Amendment No. 1 in the future.

4. Counterparts.

This Letter Amendment No. 2 may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal E-SIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

Very truly yours,

Chondrial Therapeutics IP, LLC

By: /s/ Jennifer S. Johansson

Name: Jennifer S. Johansson

Title: Vice President of Regulatory Affairs and Counsel

ACCEPTED AND AGREED TO
as of the date first above written:

Wake Forest University Health Sciences

By: /s/ Gregory L. Burke

Name: Gregory L. Burke, M.D., M.Sc.

Title: Chief Science Officer

LICENSE AGREEMENT

This License Agreement (the “Agreement”) is effective as of this 30th day of November, 2016 (the “Effective Date”) between Indiana University Research and Technology Corporation, having a place of business at 518 Indiana Avenue, Indianapolis, Indiana 46202 (“IURTC”) and Chondrial Therapeutics IP Holdings, LLC (f/k/a Chondrial Therapeutics, LLC), having its principal offices at 4500 East 75th Street, Indianapolis, Indiana 46250 (“Chondrial”).

WHEREAS, Ronald Mark Payne, Clifford M. Babbey, Gregory R. Wagner, and P. Melanie Pride at Indiana University (“IU”) invented certain patent and patent applications useful for, among others, certain testing methods related to Friedreich’s Ataxia; and

WHEREAS, IURTC hereby represents that IU assigns its intellectual property to IURTC and that IURTC is responsible for managing such intellectual property; and

WHEREAS, IURTC is willing to grant a license to Chondrial to the Licensed Patents (as defined below), subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises and covenants set forth herein, the parties hereto mutually agree as follows:

1. Definitions

For all purposes of this Agreement the following terms, whether used in the singular or plural, will have the meanings specified below:

“Affiliate” means any corporation or entity that controls, is controlled by, or is under common control with Chondrial. A corporation or other entity will be regarded as in control of or controlled by another corporation or entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity; provided that if such other corporation or entity does not have voting stock or other ownership interests, a corporation or other entity will be regarded as in control of or controlled by such other corporation or entity if it possesses, directly or indirectly, (i) the power to direct or cause the direction of the management and policies of the corporation or other entity or (ii) the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the corporation or other entity.

“Affiliate” with respect to IURTC means any entity or organization formally affiliated with IURTC and has any rights in the Licensed Patents. For the avoidance of doubt, IU is not an Affiliate of IURTC.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed,

“Biologics Act” means the Biologics Price Competition and Innovation Act, 42 U.S.C. § 262, or the equivalent law in any jurisdiction in which Chondrial commercializes or intends to commercialize Licensed Products.

“Chondrial Laboratory” means a laboratory owned, operated and funded (directly or indirectly) by Chondrial and located at such location as Chondrial will determine at its convenience.

“Commercially Reasonable Efforts” means the efforts and resources normally used by a party for a product, proposed product or technology owned by it or to which it has rights, which is of similar commercial potential at a similar stage in its development or product life, and having similar market potential, technical risk, and intellectual property protection. Commercially Reasonable Efforts will be determined by taking into account the characteristics of the product, proposed product or technology, the technical risk and stage of research, development, or commercialization of the product, proposed product or technology, the cost-effectiveness of efforts or resources applied towards such product, proposed product or technology, the competitiveness of alternative third party products, proposed products or technologies that are in the relevant marketplace or for which data have been publicly presented or published, the proprietary position of the product, proposed product or technology, the regulatory and business environment, the likelihood of regulatory approval and product reimbursement, the actual or projected profitability of the product, proposed product or technology, the relative potential for product liability exposure, and all other relevant factors. Commercially Reasonable Efforts will be determined on an individual product, proposed product or technology, basis, and country-by-country basis, and it is anticipated that the level of efforts and resources may change over time reflecting changes in the status of the product, proposed product or technology involved. In evaluating “commercial potential,” neither party will discount or exclude the profit sharing, milestone or other payments payable under this Agreement to the other party.

“Cover” means the making, having made, using, selling, offering for sale or importing of a material or product that would, absent a license or ownership by that person, (i) infringe a Valid Claim, (ii) infringe a Valid Claim upon that Valid Claim’s issuance, or (iii) infringe a Valid Claim but for the exception provided under 35 U.S.C. § 271(e)(1). “Covers,” “Covering,” and “Covered” have corresponding meanings.

“Effective Date” has the meaning given to it in the first sentence of this Agreement.

“Field” means the diagnosis, treatment, or prevention of mitochondrial diseases, including without limitation Friedreich’s Ataxia.

“Indiana Laboratory” means the laboratory at IU led by Dr. Mark Payne.

“Licensed Patents” means IURTC’s rights in:

- U.S. patent [***];

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed,

- PCT patent application [***] (further defined as “Subject Application”);
- All U.S. patent applications claiming priority to the above-referenced patents or applications, including without limitation divisionals, equivalent continuations, and subject matter claimed in continuations-in-part applications that is entitled to the priority filing date of any of the above;
- Foreign equivalent applications claiming priority to the above-referenced patents or applications;
- Patents issuing from any of the above-referenced applications;
- Any of the foregoing during reissue, re-examination, opposition, or post-grant review proceedings;
- Reissues and re-examinations of any of the above-referenced patents;
- Any extensions of or supplementary protection certificates referencing any of the above patents, including, without limitation, any regulatory exclusivities (including under 21 C.F.R. §§ 314 and 316) or equivalents thereof; and
- Other forms of government-issued rights substantially similar to any of the foregoing.

“Licensed Product” means any product, service, or process in the Field that the researching of, results from, development of, marketing and otherwise commercialization of, making of, production or previous production of, incorporation of, composition, manufacture, use, importation, or sale of that, is Covered by a Valid Claim in the Licensed Patents.

“Net Sales” means Chondrial’s, its Affiliates’ and their respective Sublicensees’ gross receipts for any Licensed Product, less the sum of the following:

- [***];
- [***];
- [***];
- [***]; and
- [***].

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed,

(a) No deductions may be made for commissions paid to individuals for the sale of Licensed Products, whether they are independent sales agents or regularly employed by Chondrial, nor for any other cost incurred in the manufacture, marketing, sale, distribution, shipment, promotion, advertisement, exploitation or commercialization of Licensed Products.

(b) Licensed Products will be considered “sold” when delivered, billed out or invoiced, whichever comes first. For all Licensed Products used by Chondrial as premiums to promote, market, sell or lease products or processes other than Licensed Products, the Licensed Products will be deemed to have been sold at Chondrial’s then-current published third party sales price for similar quantities.

(c) The transfer of any Licensed Product by Chondrial or one of its Affiliates to another Affiliate will not be considered a Net Sale, provided that the resale of such Licensed Product by any of the foregoing to third parties for commercial use will be included in Net Sales.

For the avoidance of doubt, disposal of any Licensed Product for, or use of any Licensed Product in, clinical trials, as free samples, or under compassionate use, patient assistance, named patient or test marketing programs or non-registrational studies or other similar programs or studies where Product is supplied or delivered without charge and with no benefit to Chondrial, will not result in any Net Sales. No Licensed Product donated by Chondrial, its Affiliates or Sublicensees to non-profit institutions or government agencies for a non-commercial purpose and with no benefit to Chondrial will result in any Net Sales. The use of any Licensed Product by Chondrial or one of its Affiliates or Sublicensees for research and development purposes will similarly not result in any Net Sales.

(d) If any Licensed Product is sold as part of a Combination Product (i.e., a product or a combination of products with at least two active ingredients, of which the manufacture, use or sale of at least one is not covered by the Licensed Patents), the Net Sales for such Licensed Product sold as part of a Combination Product will be determined by multiplying the Net Sales of such Combination Product (replacing “Licensed Product” with “Combination Product” in the definition of Net Sales above), during the applicable period, by the fraction, $A/(A+B)$, where A is the average per unit sale price of such Licensed Product when sold separately as a standalone Licensed Product in finished form in the country in which the Combination Product is sold and B is the average per unit sale price of the other active ingredients contained in the Combination Product when sold separately as standalone products in finished form in the country in which the Combination Product is sold, in each case during the applicable period or, if sales of such standalone Licensed Product did not occur in such period, then in the most recent period in which arm’s length fair market sales of such Licensed Product, as

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applicable, occurred. If such average sale price cannot be determined for such Licensed Product or any of the other active ingredients, the Net Sales amount will be mutually agreed upon by the parties, based on the relative value contributed by each component, such agreement not to be unreasonably withheld, conditioned or delayed. Notwithstanding anything in this Definition of Net Sales (d), a product comprised of Licensed Products under this Agreement and licensed products under the license agreement between Wake Forest University Health Sciences and Chondrial with effective date November 30, 2016 is not a Combination Product.

“Non-patent Countries” means all countries or territories of the world other than Patent Countries.

“Option Invention” means an invention that is made under a sponsored research agreement between IU and Chondrial for research conducted in the Indiana Laboratory.

“Option Period” means six (6) months from IURTC’s disclosure to Chondrial of an Option Invention.

“Patent Countries” means countries and territories in which there exists at least one Valid Claim of a Licensed Patent.

“Patenting Costs” means all reasonable costs for the preparation, filing, prosecution and maintenance of the Licensed Patents during the Term.

“Sublicense” means the grant by Chondrial or its Affiliate(s) or Sublicensees to a non-Affiliate third party (other than IURTC or IU) of a sublicense under the Licensed Patents, either exclusive or non-exclusive, to practice some or all of the rights granted to Chondrial under this Agreement.

“Sublicense Consideration” has the meaning set forth in Section 3.3.

“Sublicensee” means any non-Affiliate third party to which Chondrial or its Affiliates or any of their respective Sublicensees grants a Sublicense.

“Term” has the meaning given to it in Section 10.1. “U.S.” means the United States of America.

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“Valid Claim” means a claim of a patent that has not been held unpatentable, permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. If a claim of a pending patent application has not issued as a claim of an issued patent within five (5) years following the first office action for such application, such claim will cease to be a Valid Claim unless and until such claim is granted.

“WFUHS Consideration” means the consideration Chondrial owes to Wake Forest University Health Sciences pursuant to the license agreement between Wake Forest University Health Sciences and Chondrial with effective date November 30, 2016 that corresponds to the financial terms of this Agreement in Section 3.1-3.4.

2. Grant of License

2.1 Subject to the terms and conditions of this Agreement, IURTC hereby grants to Chondrial and its Affiliates, and Chondrial, on behalf of itself and its Affiliates, accepts from IURTC, (i) for the Term an exclusive worldwide right and license under the Licensed Patents to research, develop, market and otherwise commercialize, make, have made, use, import, offer for sale and sell the Licensed Products for the treatment, diagnosis, and prevention of disease in the Field, including the full right to Sublicense through multiple tiers of Sublicensees, in accordance with Section 4.2, any and all such rights and license; and (ii) for the Option Period a non-transferable, exclusive option to negotiate in good faith for a royalty-bearing, worldwide, exclusive license, including the right to Sublicense, to practice any and all the rights under the Option Inventions (the “Option”), in accordance with the procedures described in Section 6 hereof.

2.2 In accordance with 35 U.S.C. §§ 200-212, 37 C.F.R. Part 401, and in the relevant government research contracts with IU, the U.S. government retains certain rights and may impose certain requirements with respect to subject inventions as that term is defined therein. To the extent applicable, such rights and requirements include without limitation: (i) the grant of a nonexclusive, non-transferable, irrevocable, fully paid-up license to practice or have practiced for or on behalf of the government the subject inventions throughout the world; and (ii) the requirement that subject inventions and products produced through the use of subject inventions that are used or sold in the U.S. be manufactured substantially in the U.S, unless a suitable waiver is obtained. The rights granted in this Agreement are expressly made subject to these laws and regulations as they may be amended from time to time, and Chondrial agrees to comply and enable IURTC and IU to comply with all such laws and regulations, including without limitation to submit information requested by IURTC to satisfy IU’s reporting requirements in connection therewith. Chondrial represents and warrants that, as of the Effective Date, it, all Affiliates, and all Sublicensees constitute a “small business firm” as defined in 15 U.S.C. §632, and Chondrial will promptly notify IURTC of any change thereof that occurs during the Term.

***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed,

2.3 Notwithstanding the right and license granted in Section 2.1, Chondrial's right and license is subject to IURTC's and IU's right to research, develop, import, make, have made and use Licensed Products and practice the Licensed Patents for their own educational, academic, testing, clinical and research purposes, including the right to collaborate with other non-commercial entities for any non-commercial purposes. Without limiting the generality of the foregoing, neither Licensor nor any of their respective Affiliates may participate directly or indirectly in producing any products which are sold to any person.

2.4 Except as expressly provided for in this Agreement, no license or other rights, either express or implied, are granted by IURTC or IU to Chondrial by the execution of this Agreement or the transfer of any materials or information hereunder.

2.5 Chondrial will mark or have marked the packaging of all Licensed Products sold in the U.S. with the applicable Licensed Patents and in a manner not inconsistent with 35 U.S.C §287(a), and will mark all Licensed Products sold in other countries with the applicable Licensed Patents in a manner not inconsistent with the laws and regulation then applicable in each such country Chondrial acknowledges that it will be liable to IURTC for infringement damages lost due to a failure to mark Licensed Products and/or due to the improper or defective marking of the Licensed Patents subject to Section 7.3.

3. License Fees, Royalties and other Consideration

3.1 Royalty. In partial consideration for the rights, license and Option granted under this Agreement, Chondrial will pay to IURTC a royalty of (i) ***] of Net Sales by Chondrial, Affiliates, or Sublicensees in Patent Countries or (ii) ***] of Net Sales by Chondrial, Affiliates, or Sublicensees in Non-Patent Countries.

3.2 Sublicense Fee. In partial consideration for the rights, license and Option granted under this Agreement, Chondrial will pay to IURTC the following percentages of any and all Sublicense Consideration as described in Section 3.1 above, subject to Section 3.5:

3.2.1 ***] during the period from the Effective Date through such time as Chondrial is obligated to pay IURTC the milestone referred to in Section 3.4 (a); or

3.2.2 ***] during the period commencing upon the occurrence of the event referred to in Section 3.2.1 above through such time as Chondrial is obligated to pay IURTC the milestone referred to in Section 3.4 (b); or

3.2.3 ***] during the period commencing upon the occurrence of the event referred to in Section 3.2.2 above and continuing thereafter during the Term.

3.3 For purposes of this Agreement, "Sublicense Consideration" means ***]. For the removal of doubt, Sublicense Consideration excludes ***].

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed,

For the further removal of doubt, to the extent a Sublicense agreement includes the grant of rights unrelated to the rights to the Licensed Patents and unrelated in any way to the Licensed Products, “Sublicense Consideration” will only include a portion of amounts paid by a Sublicensee equal to the proportional value of the Licensed Patents and Licensed Products relative to the value of the other unrelated rights granted to such Sublicensee in such Sublicense agreement.

3.4 Milestones. In partial consideration for the rights, license and option granted under this Agreement, Chondrial will pay to IURTC the following amounts upon the achievement of the following events:

- (a) Enrollment of the first patient in the first Phase I (or its non-U.S. equivalent) clinical trial of a Licensed Product: [***];
- (b) [***]: [***];
- (c) [***]: [***];
- (d) [***]: [***]

3.4.1 The events listed in this Section 3.4 (a) – (d) are intended to be sequential and reflect the presumed path that a Licensed Product will take through the regulatory approval process. If any of these events does not occur for any reason, the fee due upon that skipped event(s) will be due upon the achievement of the subsequent event (and in no event later than the first commercial sale of the first Licensed Product).

3.5 In the event that Chondrial is required to pay WFUHS Consideration, then Chondrial may deduct [***] of such WFUHS Consideration from the consideration due to IURTC under Sections 3.1-3.4.

3.6 In partial consideration for the rights granted under the option agreement among Chondrial, IURTC, and WFUHS dated February 14, 2014, Chondrial will issue to IURTC 3,647 Common Units of Chondrial Therapeutics Holdings, LLC (“Chondrial Holdings”). In connection with the issuance of the Common Units to IURTC, IURTC will be required to execute an Investors’ Rights Agreement, Right of First Refusal and Co-Sale Agreement, and Amended and Restated Limited Liability Company Agreement, substantially in the forms attached hereto as Exhibits A-C, respectively, which will be executed concurrently with the execution of this Agreement.

4. Sublicenses

4.1 Upon termination of this Agreement, Chondrial will promptly notify its Affiliates extended rights under Section 2.1 and Sublicensees of such termination. Any rights previously granted by Chondrial under Section 2.1 will not be automatically terminated, provided, however, that any Sublicensee who desires to continue its Sublicense advises IURTC in writing within thirty (30) days following the effective date of termination of this Agreement of its desire to continue the Sublicense and agreement to be bound to IURTC on substantially the same terms and conditions, including without limitation financial terms, as Sublicensee was bound to Chondrial under the Sublicense, but only to the extent that each financial term is no less favorable to IURTC than those set forth in Section 3 and Section 9.4, and provided that the Sublicense does not impose any obligations on IURTC in excess of those imposed under this Agreement. If any Sublicensee desires to continue its Sublicense upon termination of this Agreement, it will be wholly the responsibility of that Sublicensee to notify IURTC of such desire within thirty (30) days after the effective date of termination of this Agreement. IURTC hereby agrees to enter into such written license agreement, with modifications negotiated in good faith as is reasonably necessary to accommodate the functional and structural differences between Chondrial and IURTC. Time is of the essence for a Sublicensee to provide notice of its desire for such license and to negotiate in good faith in a timely manner to effectuate a license. Failure of a Sublicensee to timely provide such notice or enter into such license will automatically result in the termination of the Sublicense and all rights granted thereunder or hereunder.

4.2 Sublicensee may grant further Sublicenses provided it notifies IURTC in writing prior to executing the Sublicense. Sublicensee's failure to notify IURTC prior to executing such Sublicense may, in IURTC's sole discretion, render such Sublicense invalid. All terms and conditions applicable to Sublicensee hereunder will also apply to Sublicensee's Sublicensee. All terms and conditions applicable to Sublicensee hereunder will also apply to Sublicensee's Sublicense.

4.3 All Sublicenses will contain appropriate provisions in accordance with the obligations of Chondrial to, and the rights of IURTC and IU under this Agreement. Each Sublicense will be consistent with the terms and conditions of this Agreement, including without limitation Section 7 (Disclaimer) and Section 11.4, and will:

- (a) Contain the terms and conditions set forth in Section 3.1 (Royalty) and the definitions it references therein, and in Sections 2.2, 2.3, 2.5, 8.3, and 19.2, and in Sections 13 and 16 modified only to indicate that Sublicensee is under the same obligations as Chondrial;
- (b) Contain the terms and conditions set forth in Sections 15 and 12, modified only to indicate that the Sublicensee is obligated to IURTC and IU as Chondrial is obligated to IURTC and IU hereunder; and
- (c) State that if Chondrial enters bankruptcy or receivership, voluntarily or involuntarily, then upon notice from IURTC, each Sublicensee will pay Sublicensee's royalties on Net Sales and Sublicensing Revenue then or

thereafter due directly to IURTC for the account of Chondrial. IURTC will remit to Chondrial any amounts received that exceed the sum actually owed by Chondrial to IURTC.

4.4 Chondrial will provide notice to IURTC of any Sublicense granted and will provide a copy of all such Sublicenses within thirty (30) days after execution. Chondrial will promptly provide IURTC with true and accurate copies of all reports received from a Sublicensee related to the calculation of any consideration payable to IURTC hereunder.

4.5 Chondrial agrees to use Commercially Reasonable Efforts to cause Sublicensees to perform their obligations as Sublicensees. To the extent Chondrial becomes aware of an act or omission by a Sublicensee that would be a breach of this Agreement if imputed to Chondrial and fails to use Commercially Reasonable Efforts to cause Sublicensee to cure or mitigate such breach, then the act or omission will be deemed to be a breach by Chondrial of this Agreement. At IURTC's sole discretion, IURTC may require Chondrial to terminate any Sublicense should Sublicensee fail to cure or mitigate such breach. Chondrial's termination of the Sublicense will be considered Chondrial's cure of Chondrial's deemed breach under this Section 4.5.

5. Diligence

5.1 Chondrial will use Commercially Reasonable Efforts to bring the Licensed Products to market through exploitation of the Licensed Patents and commercialization of the Licensed Products.

5.2 Without limiting the generality of the diligence provisions of Section 5.1 above, Chondrial will achieve (either itself or through its Affiliates and/or its Sublicensees) the following milestones by the following dates ("Milestones"):

- (a) Chondrial will have at least two full-time equivalent personnel working on the development, manufacturing and marketing of the Licensed Products within the twelve (12) month period from the Effective Date and each subsequent year thereafter;
- (b) Enrollment of the first patient in the first Phase I (or its non-U.S. equivalent) clinical trial of a Licensed Product within thirty (30) months from the Effective Date;
- (c) Enrollment of the first patient in the first Phase II (or its non-U.S. equivalent) clinical trial of a Licensed Product within sixty (60) months from the Effective Date;

5.2.1 Chondrial will provide to IURTC (at the time of the next due report under Section 8) written notice of the achievement of each Milestone in this Section 5.2 (and continued confirmation of Chondrial's sustained achievement of Section 5.2(a)).

5.3 Chondrial will use Commercially Reasonable Efforts to have the Licensed

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Products cleared for marketing in those countries in which Chondrial, in its sole discretion, intends to sell Licensed Products by the responsible governmental agencies requiring such clearance. To accomplish such clearances at the earliest possible date, Chondrial will file, according to the usual practice of companies similarly situated to Chondrial, any necessary data with such governmental agencies. For clarity, the development and commercialization of the Licensed Products outside of the U.S. is at Chondrial's sole discretion.

5.4 If IURTC is approached by a bona fide third party about development of an application of the Licensed Patents that is within the Field but is not currently being developed by Chondrial, IURTC will notify Chondrial of the inquiry.

6. Option

6.1 When an Option Invention is disclosed to IURTC, IURTC will promptly forward a copy to Chondrial, whereupon Chondrial will have the Option Period to exercise the Option to license IURTC's rights in the Option Invention. Any such disclosure will be considered IURTC Confidential Information under Section 13.

6.2 The Option granted in Section 2.1 expressly does not include the right to practice the Licensed Patents or other intellectual property in any other way not expressly provided for in this Section 6.

6.3 Any license entered into between Chondrial and IURTC pursuant to the Option granted in Section 2.1 above will (i) be negotiated in good faith by the parties and, with the exception of Sections 3.5 and 9.8, will follow the economic and legal terms and conditions contained in this Agreement; (ii) be exclusive, worldwide, and royalty-bearing; (iii) include the right to sublicense; (iv) provide for the IURTC and IU's continued right to make, have made, use or practice the Option Inventions for their noncommercial research, clinical, academic and educational purposes and to collaborate with other academic and non-commercial entities for such purposes; (v) be limited by any rights of the U.S. government that may arise out of the U.S. government's sponsorship of research leading to the Option Inventions; and (vi) unless otherwise agreed by the parties, include provisions that substantially conform to the provisions of Sections 4, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18 and 19 of this Agreement. All terms and conditions of such license agreement will be negotiated in good faith by the parties prior to any research, commercial development or practice of the Option Inventions.

7. Disclaimer of Warranties and Representations

7.1 Except as set forth in this Agreement, all property, whether tangible or intangible, which may be delivered hereunder, will be delivered on an "as is, where is" basis without any express or implied representation or warranty.

7.2 EXCEPT AS SET FORTH IN THE RECITALS TO THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS NOR EXTEND ANY WARRANTIES WHATSOEVER AND HEREBY DISCLAIM ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, IMPLIED REPRESENTATIONS AND WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY IMPLIED REPRESENTATIONS AND WARRANTIES ARISING FROM ANY COURSE OF DEALING, USAGE OR TRADE PRACTICE. IURTC MAKES NO REPRESENTATIONS OR WARRANTIES, AND EXPRESSLY DISCLAIMS ON BEHALF OF ITSELF AND IU ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, STATUTORY, IMPLIED, OR OTHERWISE, INCLUDING WITHOUT LIMITATION DIRECTLY OR INDIRECTLY OPERATING OR APPLYING AS A WAIVER OF SOVEREIGN IMMUNITY BY IU OR THE STATE OF INDIANA. IURTC, AND IU ASSUME NO RESPONSIBILITY WITH RESPECT TO THE EXPLOITATION OR COMMERCIALIZATION OF THE LICENSED PATENTS OR THE MANUFACTURE, USE, SALE, LEASE OR DISTRIBUTION OF ANY METHODS, PROCESSES, APPARATUS, DEVICES, SYSTEMS, PRODUCTS, ARTICLES AND APPLIANCES DERIVED FROM OR USING THE LICENSED PRODUCTS BY CHONDRIAL.

7.3 NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR LOSS OF PROFITS, LOSS OF USE OR ANY OTHER DIRECT, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES EXCEPT AS PROVIDED IN SECTION 2.5.

8. Records, Reports and Payments

8.1 Chondrial will keep and maintain and will require any and all of its Affiliates, and their respective Sublicensees to keep and maintain complete, accurate and correct records and books relating to the sale, lease, use or disposition of the Licensed Products and any and all payments or consideration associated with this Agreement for at least three (3) years following the end of the calendar year to which such records and books pertain.

8.2 Chondrial will provide to IURTC written reports annually from the Effective Date of this Agreement until the first commercial sale of a Licensed Product, and thereafter for each calendar quarter as of January 1, April 1, July 1 and October 1 of each calendar year during the remaining Term of this Agreement, the written reports to be provided within forty-five (45) days of the end of each such period, setting forth the following information:

- (a) Milestones achieved, Sublicenses signed, Affiliates developed;
- (b) accounting for any and all Licensed Products sold, distributed, transferred, used or leased;
- (c) gross receipts of Licensed Products, the serial numbers of the patent applications and patents of the Licensed Patents that may cover each Licensed Product;

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- (d) any applicable deductions, allowances and charges as provided in the definition of Net Sales;
- (e) total Net Sales; and
- (f) total royalties, sharing of Sublicense Consideration and any other payments or consideration under this Agreement then due.

8.2.1 Chondrial will give to IURTC with each such report and on the date specified above the full amount of any and all payments due, provided that if Chondrial in good faith has a *bona fide* dispute with respect any such payment it will be required to pay only such amount which is not in dispute and the disputed amount will be placed in escrow as described below. Following the date of first commercial sale of a Licensed Product, if no sales or leases of the Licensed Products were made during any calendar quarter, Chondrial will provide to IURTC a statement to that effect. Prior to the first commercial sale of a Licensed Product, Chondrial will annually provide IURTC with a brief summary of progress made by Chondrial, its Affiliates and their respective Sublicensees towards the commercialization of the Licensed Products. If Chondrial disputes the amount of payment, the payments payable to IURTC will be placed in an escrow account during the pendency of such action for distribution to the prevailing party.

8.3 The books and records of account kept by Chondrial pursuant to Section 8.1 above will be made available upon reasonable notice, during normal business hours for examination by one or more independent auditors of IURTC's choosing, reasonably acceptable to Chondrial, who will be permitted to enter upon the premises of Chondrial to examine such books and records to verify all amounts payable to IURTC under this Agreement and make and retain copies of any and all parts of said books and records of account, including invoices that are relevant to any report required to be rendered by Chondrial; provided, however, that such examination will occur no more than once per calendar year and that such auditor(s) will enter into confidentiality agreements reasonably acceptable to Chondrial. Said copies will be provided to the auditor without cost to Chondrial. All payments not paid by Chondrial to IURTC when due will accrue interest, from the due date until payment is received by IURTC, at an annual rate equal to [***] above the prime rate published in the Eastern edition of The Wall Street Journal at the beginning of the period of arrearage (or the maximum allowed by law, if less). In the event of default in payment, collection agency's fees of the delinquent balance and out-of-pocket attorney fees plus any applicable court costs will be added to the amount due to IURTC. Chondrial will reimburse IURTC within fifteen (15) days of each invoice for all such costs, and any interest on such costs will accrue at the rate described above with respect to late payments. Any amount found to have been paid but not owed will be credited toward future payments owed by Chondrial. In the event any such audit shows that Chondrial has underpaid or overpaid its royalty obligation hereunder by [***] or more, during any calendar year, Chondrial will reimburse IURTC for IURTC's reasonable out-of-pocket expenses for such audit.

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8.4 Royalty or other payments will be paid in U.S. Dollars to IURTC in Indianapolis, Indiana, or at such other place as IURTC may reasonably designate consistent with the laws and regulations controlling in any foreign country. If any royalties hereunder are based on sales converted from foreign currency, such conversion will be made by using the exchange rate published in the U.S. edition of the Wall Street Journal on the last day of the calendar quarter period to which such royalty payments relate.

8.5 If laws or regulations require that any other taxes be withheld by Chondrial from any payments hereunder, the parties will determine how the appropriate tax payment can be made and take appropriate steps to ensure that such payments be made, it being understood that Chondrial will use its Commercially Reasonable Efforts to cooperate with IURTC to minimize any such amounts to be withheld and Chondrial, upon written request from IURTC, will provide IURTC with all documents necessary for IURTC to seek any potential refunds.

8.6 Each party will keep the other parties fully informed promptly as to all issues relating to the safety, toxicity, efficacy and pharmacokinetics of all Licensed Products, and all research and development related thereto as to which such party has knowledge whether by way of its own research and development of Licensed Products, or that of its Affiliates or Sublicensees, or any other person who has had access thereto. For clarity, this provision is not to be interpreted as an obligation for IURTC to seek out issues related to safety, toxicity, efficacy, or pharmacokinetics, but only to inform Chondrial should it become aware of any such issues. Chondrial's sole remedy, should IURTC breach this Section 8.6, is termination under Section 10.2.3.

9. Patent Prosecution

9.1 IURTC will prepare, file, prosecute, defend, and maintain the Licensed Patents in its discretion in accordance with the terms and conditions herein. IURTC will instruct its attorneys to keep Chondrial informed of patent prosecution in the Field and to seek Chondrial's comments and suggestions prior to taking material actions for the same (provided Chondrial is not in breach of this Agreement). Provided Chondrial is not in breach of this Agreement and subject to Section 9.12, IURTC will not abandon, cease prosecution or reduce the scope of any Licensed Patent without first notifying Chondrial in writing at least sixty (60) days in advance of any filing or maintenance deadline, and Chondrial will have the right, but not obligation, to assume such activities at Chondrial's sole cost and expense.

9.2 IURTC will authorize Chondrial to communicate directly with IURTC's patent counsel. All information exchanged among IURTC's counsel, the Parties, and/or the Inventors regarding the preparation, filing, prosecution, issue, defense, or maintenance of the Licensed Patents will be deemed Confidential Information of IURTC. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution, issue, defense, and maintenance of the Licensed Patents, the interests of the Parties as licensor and licensee are to obtain the strongest and broadest patent protection possible, and as such, are aligned and legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Patents, including without limitation, privilege under the common interest doctrine and similar or related doctrines.

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9.3 Chondrial will have the right to approve patent counsel chosen by IURTC, which approval will not to be unreasonably withheld. Upon Chondrial's written request, which will not be made more than once a year, IURTC will provide a written report to Chondrial to inform Chondrial of projected costs associated with the filing, prosecution or maintenance of any U.S. or foreign patent applications or patents within the Licensed Patents. If Chondrial determines that any filing, prosecution or maintenance cost is not justified, it will advise IURTC in writing within thirty (30) days from receipt of the written report and the parties will discuss the matter in good faith, taking into consideration and giving significant weight to Chondrial's marketing and commercialization plans.

9.4 Chondrial will reimburse IURTC forty-three thousand three hundred seventy-seven dollars and eighty-one cents (\$43,377.81) within fifteen (15) days after the Effective Date for expenses incurred prior to the Effective Date for the Licensed Patents.

9.5 During the Term, Chondrial will reimburse IURTC for all reasonable and documented costs and expenses incurred by IURTC relating to the Licensed Patents within sixty (60) days of receipt of billing invoices for such costs and expenses.

9.6 Notwithstanding anything to the contrary herein:

9.6.1 IURTC may request written confirmation from Chondrial that it will satisfy its reimbursement obligations for any particular fees or expenditures for the Licensed Patents at least sixty (60) days in advance of the date on which such expenditure is reasonably anticipated to be made or such fee is due to be paid. If Chondrial elects not to pay in accordance with Section 9.6 or fails to respond, then such Licensed Patents will be removed from the Agreement, the license granted to Chondrial for those patent applications or patents in the Licensed Patents will terminate, the definition of Licensed Patents will be unilaterally amended to exclude such rights, and IURTC will be free, at IURTC's sole discretion and without any further obligation to Chondrial regarding such former Licensed Patents, including without limitation, to prosecute and maintain for IURTC's sole use and benefit, to license or to abandon the patent applications or patents;

9.6.2 In addition, IURTC may, at its sole discretion, require payment of a retainer from Chondrial for filing fees prior to filing patent applications in foreign countries, foreign annuities, or other direct costs paid on behalf of IURTC for the Licensed Patents to any patent office; and

9.6.3 During any period in which Chondrial is in breach of this Agreement and IURTC has served notice to Chondrial of such under Section 10.2, IURTC may, at its sole discretion, require Chondrial to pay in advance for actions undertaken by counsel regarding the Licensed Patents; and in addition to and not in lieu of its other rights and remedies hereunder, IURTC will have no obligations to Chondrial under this Section 9 if Chondrial has not paid in advance and has not cured its breach under this Section 9.

9.7 If Chondrial elects not to incur fees or expenditures for any Licensed Patents, Chondrial will give IURTC written notice of such election at least sixty (60) days in advance of the date on which such expenditure is to be made or such fee is due to be paid. Upon IURTC's receipt of such notice, or if any payment due under this Section 9 is delinquent for more than thirty (30) days, the license granted to Chondrial for those patent applications or patents in the Licensed Patents will terminate, the definition of Licensed Patents will be unilaterally amended to exclude such rights, and IURTC will be free, at IURTC's sole discretion and without any further obligation to Chondrial regarding such former Licensed Patents, including without limitation, to continue prosecution and maintenance for IURTC's sole use and benefit, to license or to abandon the patent applications or patents.

9.8 As between the Parties, Chondrial will have sole discretion on whether to seek to obtain patent term extensions, including without limitation extensions provided under U.S. law at 35 U.S.C. §154(b) and 156, and foreign supplementary protection certificates, with respect to any of the Licensed Patents. Chondrial hereby agrees to provide IURTC with all necessary assistance in securing such extension, including without limitation, providing all information regarding applications for regulatory approval, approvals granted, and the timing of same.

10. Termination

10.1 Unless sooner canceled or terminated as herein provided, this Agreement will continue until the last to expire Valid Claim within the Licensed Patents (including any period of regulatory exclusivity thereof), unless earlier terminated as set forth herein (the "Term"), subject to the royalty rates on a country-by-country basis as set forth in Section 3.

10.2 If either party commits a breach of any material covenant or obligation set forth herein, the other party will have the right, in addition to all other remedies available, to terminate this Agreement by giving the other party sixty (60) days prior written notice of such termination, provided, however, that if such other party will have rectified such default or breach within such 60-day period, this Agreement will remain in effect and in force as if no default or breach had occurred. With respect to Chondrial's material breach of this Agreement, "material breach" includes without limitation a material failure to: (i) timely pay any fee, royalty, or other payment required under Article 3, Section 8.3, Article 9, or Section 11.2, and including without limitation any interest on and fees and costs attributable to the collection of late payments under Section 8.3; and (ii) timely provide reports or notices under Sections 2.2, 4.4, 5.2.1, 8.2, 8.5, and with respect to the Sublicensee, 4.1, and the successor, 14.1.3; (iv) failure to obtain, maintain, or timely report levels of insurance under Article 12; (v) failure to provide notice or to include all required terms in Sublicenses or inclusion of any terms prohibited under Sections 4.2 and 4.3; and (vi) failure to indemnify IURTC Indemnitees or properly inform or involve IURTC under Article 12.

10.2.1 If, during such 60-day period, Chondrial demonstrates to IURTC's reasonable satisfaction that Chondrial is diligently pursuing a cure to the breach but requires additional time to achieve such cure, Chondrial and IURTC will promptly meet to agree upon an extension to the cure period that would allow Chondrial adequate time to cure the breach.

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10.2.2 IURTC may terminate this Agreement under Section 10.2 if Chondrial at any time (a) ceases to carry Director's and Officer's insurance with coverage levels appropriate for Chondrial's then-current stage of development or (b) ceases to have at least two full-time equivalent personnel working on the development, manufacturing and marketing of the Licensed Products.

10.2.3 Chondrial may terminate this Agreement effective immediately if, in its reasonable opinion as supported by test results or other means, the Licensed Products, or the products likely to be produced under the Licensed Products pose a serious issue involving safety, toxicity, efficacy or pharmacokinetics.

10.2.4 Notwithstanding the sixty (60) day cure period above, IURTC may terminate this Agreement by giving Chondrial fifteen (15) business days prior written notice of such termination for failure to pay any fees and expenses under Section 9, provided however, provided, however, that if Chondrial will have rectified such default or breach within such 15-day period, this Agreement will remain in effect and in force as if no default or breach had occurred.

10.3 To the extent permitted by applicable law, if Chondrial becomes bankrupt or insolvent, or files a petition in bankruptcy, or if the business of Chondrial is placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of Chondrial or otherwise, the Agreement and any and all rights granted thereunder will automatically terminate without any notice whatsoever to Chondrial.

10.4 Chondrial will have the right to terminate this Agreement with or without cause upon sixty (60) days' written notice to IURTC.

10.5 If at any time Chondrial directly or indirectly disputes or assists any third party to dispute the validity of any patent comprising the Licensed Patents, (i) Chondrial is not relieved of its obligations in Section 9.4 and (ii) the royalties payable to IURTC under Section 3 hereunder will be placed in an escrow account during the pendency of such action disputing the validity of the Licensed Patents, for distribution to the prevailing party.

10.6 As of the date of termination of this Agreement by any party for any reason under the terms herein, including expiration of the Term, all rights granted by IURTC will terminate and automatically revert to IURTC. Upon termination other than through expiration of this Agreement, Chondrial agrees not to practice or permit another to practice the Licensed Patents. All terms and conditions herein that, by their express terms or by implication, are to be performed after the termination of this Agreement or are prospective in nature will survive termination, as the case may be, and Chondrial's obligations to pay fees, royalties, or other payments and patent expenses accruing prior thereto. Upon expiration or termination of this Agreement for any reason, nothing herein will be construed to release either party from any obligation accrued prior to the effective date of such termination.

11. Infringement

11.1 Each party will promptly inform the other in writing of any alleged infringement by a third party or other unauthorized party of any of the patents comprising the Licensed Patents, and provide such other party with any available evidence of infringement. Chondrial will not settle or compromise any claim or action, including without limitation any declaratory judgment action alleging invalidity or noninfringement of any of the Licensed Patents, in a manner that imposes any restrictions, limitations, responsibilities or obligations on IURTC and/or IU (as appropriate) without IURTC's express written consent, which will not be unreasonably withheld.

11.2 During the Term, Chondrial will have the first right, but not the obligation, to prosecute at its own expense any such infringements of the Licensed Patents and, in furtherance of such prosecution, Chondrial may join IURTC (as appropriate) as a party plaintiff in any such suit, without expense to IURTC. Similarly, during the Term, Chondrial will have the right to defend at its own expense any declaratory judgment action alleging invalidity or non-infringement of any of the Licensed Patents, and, in furtherance thereof, Chondrial may join IURTC (as appropriate) as a party in any such suit, without expense to IURTC. The total cost of any such action commenced or defended solely by Chondrial will be borne by Chondrial. Any recovery of damages by Chondrial as a result of such action will be applied first in satisfaction of any reasonable unreimbursed expenses and attorneys' fees of Chondrial relating to the action. The balance remaining from any such recovery will be distributed to Chondrial, provided that Chondrial will pay to IURTC such royalties as would otherwise be applicable under Section 3.1 hereof for that portion of Chondrial's recovery attributable to lost sales, payments or revenues.

11.3 If, within One Hundred Eighty (180) days after having been notified in writing of any alleged infringement, Chondrial has been unsuccessful in persuading the alleged infringer to desist, or has not brought, or otherwise is not diligently prosecuting, an infringement action, or if Chondrial notifies IURTC at any time prior thereto of its intention not to bring suit against any alleged infringer, then, and in those events only, IURTC will have the right, but not the obligation, to prosecute at its own expense any infringement of the Licensed Patents. Settlement, consent judgment or other voluntary final disposition of the suit may be entered into by IURTC without the consent of Chondrial, provided, however that IURTC will not settle or compromise any claim or action, including without limitation any declaratory judgment action alleging invalidity or non-infringement of any of the Licensed Patents, in a manner that imposes any monetary obligations on Chondrial, without Chondrial's express written consent. The total cost of any such infringement action commenced or defended solely by IURTC will be borne by IURTC, and IURTC will keep any recovery or damages, for past infringement or otherwise, derived therefrom.

11.4 In any infringement suit brought or declaratory judgment action defended by either party to protect any of the Licensed Patents pursuant to this Agreement, the other party will, at the request and expense of the party controlling such suit and at such party's expense, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens and the like.

12. Indemnification and Insurance

12.1 Chondrial will indemnify, defend, and hold harmless IURTC, IU, their respective affiliates, Board of Directors, trustees, employees, faculty, staff, students, Inventors, successors, assigns, independent contractors, and agents (collectively, "IURTC Indemnitees") from and against any and all judgments, liabilities, losses, damages, actions, claims, costs, or expenses (including without limitation all attorney fees and costs incurred by IURTC Indemnitees) (collectively, "Losses") arising out of or relating to the exercise of any rights conveyed under this Agreement and/or by Sublicense, breach of any term or condition under this Agreement and/or Sublicense, and/or the negligence, willful malfeasance, and/or willful misconduct by Chondrial and/or Affiliates, successors, assigns, or Sublicensees, including without limitation:

12.1.1 The use of any Licensed Patents, including without limitation, in the design, development, production, manufacture, sale, offer for sale, use, importation, exportation, lease, marketing, or promotion of any Licensed Product;

12.1.2 Product liability, injury or death to any person, damage to property, or any injury to business, including without limitation, business interruption or damage to reputation, arising out of and/or relating to the use of the Licensed Patents or a Licensed Product; and

12.1.3 Any third party claim that any use of Confidential Information or licensing of the Licensed Patents, or development, provision, or use of Licensed Products violates or infringes a third party's intellectual property rights; except to the extent of the Losses that are solely attributable to the breach, negligence, recklessness, willful malfeasance, or willful misconduct of IURTC.

12.2 Chondrial at its sole expense will defend third party claims with respect to Section 12.1. Chondrial will have the right to conduct the defense of such actions through outside counsel of its choice which is reasonably acceptable to IURTC. Chondrial will consult with IURTC prior to and in conjunction with all significant issues, will keep IURTC informed of all proceedings, and will provide copies to IURTC of all pleadings, legal analyses, and other papers related to such actions. IURTC will provide reasonable assistance to Chondrial in defending any such actions, and IURTC Indemnitees may be represented by counsel of its choosing at its expense. Chondrial will not settle or compromise any claim or action in a manner that admits the fault of, imposes restrictions, or creates obligations on IURTC Indemnitees or requires any financial payment or admission of liability by IURTC Indemnitees.

12.3 If Chondrial fails to defend a claim or action within twenty (20) days of learning of the same, in addition to and not in lieu of other rights and remedies, IURTC may assume the defense for the account of and at the risk of Chondrial, and any resulting liability, including attorney fees, will be deemed conclusively to be a liability of Chondrial. Chondrial's failure or refusal to act is a material breach of this Agreement.

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12.4 Chondrial, Affiliates extended rights under Section 2.1, and Sublicensees will obtain and maintain commercial general liability insurance with a reputable and financially secure insurance carrier prior to clinical testing, making, using, importing, offering to Sell, or Selling any Licensed Product or engaging in any other act involving any Licensed Product or the Licensed Patents, if such act could possibly create risk of a claim against IURTC Indemnitees for personal injury or property damage.

12.4.1 The insurance will identify IURTC Indemnitees as additional insureds and will provide that the carrier will notify IURTC in writing at least thirty (30) days prior to cancellation or material change in coverage.

12.4.2 The insurance will include coverage for product liability with a minimum of [***] per occurrence and [***] annual aggregate, coverage for contractual liability, clinical trials liability if any such trial is performed, and all other coverages standard for such policies.

12.4.3 Insurance policies purchased to comply with this Section will be kept in force for at least five (5) years after the last Sale of Licensed Product.

12.5 At IURTC's request, such request to be made no more than annually, Chondrial will provide IURTC with a certificate of insurance and notices of subsequent renewals for its insurance and that of Affiliates extended rights under Section 2.1 and Sublicensees.

12.6 The specified minimum coverages and other provisions of this Section 12 do not constitute a limitation on Chondrial's obligation to indemnify the IURTC Indemnitees under this Agreement.

13. Confidentiality

13.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, each party agrees that, during the Term and for five (5) years thereafter, such party will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as expressly provided for in this Agreement any information furnished to it by the other party pursuant to this Agreement that is marked "confidential" or which is or would reasonably be known to be confidential ("Confidential Information"). Such party (the "Receiving Party") may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party will promptly notify the other party upon discovery of any unauthorized use or disclosure of the Confidential Information. In appreciation of IU's status as an academic institution, Chondrial will take reasonable steps to limit the amount of Chondrial's Confidential Information that is shared with IURTC that which is required by this Agreement or that which IURTC needs or wants in order to enhance IURTC' performance under this Agreement.

13.2 Exceptions. Confidential Information will not include any information which the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available; (b) is known by the Receiving Party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party by a third party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party without the use of Confidential Information of the other party.

13.3 Authorized Disclosure. Each party may disclose Confidential Information of the other party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting patents as permitted by this Agreement;
- (b) prosecuting or defending litigation as permitted by this Agreement;
- (c) complying with applicable court orders or governmental regulations;
- (d) in the case of Chondrial, disclosure to a party's Affiliates, provided that Confidential Information so disclosed will remain subject to this Section 13; and
- (e) in the case of Chondrial, disclosure to third parties in connection with due diligence or similar investigations by such third parties, and disclosure to potential third party investors in confidential financing documents, provided, in each case, that any such third party agrees to be bound by reasonable obligations of confidentiality and non-use.
- (f) IURTC may report consideration received under this Agreement and Chondrial's progress under Section 8 to IU and the Inventors and to the U.S. government under Section 2.2.

Notwithstanding the foregoing, in the event a party is required to make a disclosure of the other party's Confidential Information pursuant to Section 13.3(b) or (c) it will, except where impracticable, give reasonable advance notice to the other party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. The parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by the parties with the Securities and Exchange Commission or as otherwise required by law.

14. Assignment

14.1 Chondrial may assign or otherwise transfer this Agreement and the license granted hereby and the rights acquired by it hereunder, whether voluntarily, by merger, operation of law or otherwise, only in whole and not in part, without any consent of or notice to IURTC, to an Affiliate or to the assignee or transferee of Chondrial's or its Affiliate's business or of that part of Chondrial's or its Affiliate's business to which this Agreement directly relates; provided that:

14.1.1 Chondrial is not in breach of this Agreement in any respect;

14.1.2 The successor is not materially insolvent; and

14.1.3 The successor agrees in writing (with a copy sent to IURTC within ten (10) days of the effective date of the assignment) to assume all obligations and liabilities of Chondrial to IURTC.

14.2 The rights granted in this Agreement may not be encumbered, pledged, or hypothecated in any way by Chondrial or any Sublicensee, including without limitation to secure any purchase, lease, or loan. Any conveyance in contravention with the terms and conditions of this Agreement is null and void.

14.3 This Agreement is binding on the parties and their respective successors and assigns and inures to the benefit of the parties and their respective permitted successors and permitted assigns.

15. Non-Use of Names

15.1 Neither party will use the names of the other or of the employees of such other party, IURTC or IU nor any adaptation thereof, in any advertising, promotional or sales activities without prior written consent from such other party in each separate case, except that either party may state that Chondrial licensed from IURTC one or more of the patents and patent applications within the Licensed Patents and such other nominative use of such names as will be reasonable in the circumstances. Each party will hold the specific financial terms of this Agreement (including without limitation royalty rates and measurement mechanisms and the payments called for upon milestone events) in confidence and will not disclose the same publicly without the prior consent of the other party which consent will not be unreasonably withheld or delayed. However, nothing herein will prohibit any public disclosure that is required by any applicable law or regulation or by any competent governmental authority; provided, that the party subject to such disclosure requirement will provide reasonable prior notice to the other party or in connection with corporate or financial transactions on the part of Chondrial. In addition, the parties may engage in accurate nominative use of each other's names.

15.2 IURTC and Chondrial agree to issue a mutually acceptable press release shortly after the Effective Date.

16. Export Controls

16.1 It is understood that IURTC is subject to U.S. laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities that may require a license from the applicable agency of the U.S. government or may require written assurances by Chondrial that Chondrial will not export data or commodities to certain foreign countries without prior approval of such agency. IURTC does not represent that a license is not required, or that, if required, such a license will be given.

17. Public Announcements.

17.1 The parties agree on the importance of coordinating their public announcements respecting this Agreement and the subject matter hereof (other than academic, scientific or medical publications that are subject to the provisions of any sponsored research agreement between IU and Chondrial).

18. Payments, Notices and Other Communications

18.1 Any payment, notice, or other communication pursuant to this Agreement will be sufficiently made or given on the date of mailing if sent to such party by email, overnight courier (e.g. Federal Express) or certified first class mail, postage prepaid, addressed to it at its address below or as it will designate by written notice given to the other party:

IURTC:	Vice President Office of Technology Commercialization Attn: IURTC Agreement Number 2016-0127 Indiana University Research and Technology Corporation 518 Indiana Avenue Indianapolis, IN 46202 Phone: (317) 274-5905 (not for official communications) Fax: (317) 274-5902 (not for official communications) Email: Patent prosecution: patents@iu.edu Patent cost reimbursement: licenses@iu.edu Financial consideration: licenses@iu.edu
Chondrial:	Chondrial Therapeutics IP Holdings, LLC 4500 E. 75TH Street Indianapolis, IN 46250

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Attention: Steven R. Plump

Phone: (317) 578-1596

Email: info@chondrialtherapeutics.com

19. Miscellaneous Provisions

19.1 The parties hereto acknowledge that this Agreement sets forth the entire agreement and understanding of the parties hereto as to the subject matter hereof, and will not be subject to any change or modification except by the execution of a written instrument signed by the parties hereto.

19.2 The provisions of this Agreement are severable, and in the event that any provision of this Agreement will be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability will not in any way affect the validity or enforceability of the remaining provisions hereof.

19.3 The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

19.4 This Agreement will be binding and inure to the benefit of the parties hereto and their respective affiliates, and permitted successors and assigns.

19.5 The representations, warranties, covenants, and undertakings contained in this Agreement are for the sole benefit of the parties hereto and their permitted successors and assigns and such representations, warranties, covenants, and undertakings will not be construed as conferring any rights on any other party.

19.6 Nothing contained in this Agreement will be deemed to place the parties hereto in a partnership, joint venture or agency relationship and neither party will have the right or authority to obligate or bind the other party in any manner.

19.7 This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which taken together will constitute one and the same instrument.

19.8 Each party has consulted its own counsel during the drafting of this Agreement and agrees that in the event of a dispute the language of this Agreement will not be deemed to have been drafted by either individual party.

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19.9 This Agreement will be construed, interpreted, and applied according to the laws of Indiana, without regard to its or any other jurisdiction's conflicts of laws provisions. Chondrial agrees that all claims, disputes, or controversies arising under or relating to this Agreement, including without limitation those concerning the validity, construction, or scope of any of the Licensed Patents that are not barred by sovereign immunity will be subject to the exclusive jurisdiction and venue of the state or Federal District Court seated in Marion County, Indiana. Neither Party waives its right to seek reimbursement of documented attorney fees in any action to enforce this Agreement.

19.10 As of the Effective Date, Chondrial represents and warrants that it is a small entity as defined in 37 C.F.R. 1.27, and it will promptly notify IURTC of any change to its entity status through acquisition, addition of employees, sublicensing this Agreement, or any other mechanism.

19.11 Chondrial agrees that in the event a faculty or staff member of IU serves Chondrial in the capacity of consultant, officer, employee, board member, advisor, or other designation, under contract or otherwise, such faculty or staff member is subject to compliance with IU's conflict of interest and conflict of commitment policies, including without limitation the obligation to complete a disclosure therefor, will serve solely in his or her individual capacity, as an independent contractor, and not as an agent or representative of IURTC or IU, that IURTC or IU exercises no authority or control over such faculty or staff member while acting in such capacity, that IURTC and IU receive no benefit from such activity, and that IURTC and IU assume no liability or obligation in connection with any such work or service undertaken by such faculty or staff member. Chondrial further agrees that any breach, error, act, or omission by such faculty or staff member acting in the capacity set forth above in this Section will not be imputed or otherwise attributed to IURTC or IU, including without limitation to constitute a breach by IURTC of this Agreement.

19.12 The provisions of Sections 1 (Definitions), 4 (Sublicenses), 6 (the "Option"), 7 (Disclaimer), 11 (Infringement), 12 (Indemnification), 13 (Confidentiality), 16 (Export Controls), 18 (Payments, Notices, Communication) and 19 (Miscellaneous, as relevant) survive the termination or expiration of this Agreement.

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IN WITNESS WHEREOF, the parties hereto have hereunto set their hands and seals and duly executed this Agreement as of the day and year first set forth above.

Indiana University Research and Technology Corporation

Chondrial Therapeutics IP Holdings, LLC

By: /s/ Marie C. Kerbeshian, Ph.D.

By: Chondrial Therapeutics Holdings, LLC, its sole member

Name: Marie C. Kerbeshian, Ph.D.

By: /s/ Steven R. Plump

Name: Steven R. Plump

Title: Vice President

Title: Authorized Representative

Date: 11/30/2016

Date: 11/30/2016

EXHIBIT A
CHONDRIAL THERAPEUTICS HOLDINGS, LLC
INVESTORS' RIGHTS AGREEMENT

[see attached]

[Exhibit A to License Agreement]

EXHIBIT B

**CHONDRIAL THERAPEUTICS HOLDINGS, LLC
RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT**

[see attached]

[Exhibit B to License Agreement]

EXHIBIT C

CHONDRIAL THERAPEUTICS HOLDINGS, LLC

AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

[see attached]

[Exhibit C to License Agreement]

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Exhibit 10.10

FIRST AMENDMENT
TO
LICENSE AGREEMENT

This First Amendment (the “First Amendment”) is made and entered into as of August 16, 2019 (the “First Amendment Effective Date”) by and between:

The Trustees of Indiana University (“IU”), a body politic and corporate of the State of Indiana, having its principal offices at 107 S. Indiana Ave., Bloomington, IN 47405; and

Indiana University Research and Technology Corporation (“IURTC”), a non-profit corporation organized under the laws of the State of Indiana, represented by IU; and

Chondrial Therapeutics IP, LLC (“Chondrial”), a limited liability company organized under the laws of the State of Delaware, having its principal offices at 150 Monument Rd., Suite 207, Bala Cynwyd, PA 19004.

IU, IURTC, and Chondrial hereby agree:

1. **Background:** Chondrial Therapeutics IP Holdings, LLC (f/k/a Chondrial Therapeutics LLC) and IURTC entered into the License Agreement dated November 30, 2016 with IU Agreement No. 2017-0063 (the “Agreement”). Due to a drafting error, Chondrial was incorrectly named as Chondrial Therapeutics IP Holdings, LLC in the Agreement.

Through a Third Amended and Restated Master Agreement between IU and IURTC dated October 20, 2017, IURTC authorized IU to manage, control, and be responsible for all agreements related to IURTC’s ownership rights in such these intellectual property rights, and pursuant to such agreement, IURTC assigned its rights to U.S. patent [***] and [***] to IU on July 19, 2019.

IU, IURTC, and Chondrial desire to enter into this First Amendment to amend the Agreement in consideration of the foregoing premises and the mutual promises, covenants, and agreements hereinafter set forth.

2. **Amendments:**

- 2.1. IU assumes all rights and obligations under the Agreement and is bound by all its terms in all respects as of the Effective Date of the Agreement as if it were the original licensor and original party of the Agreement in place of IURTC. For clarity, the term “IU Indemnitees” means the parties originally identified as “IURTC Indemnitees” in Section 12.1 of the Agreement and is substituted for the term “IURTC Indemnitees” wherever it appears in the Agreement. Notwithstanding the foregoing, IU and Chondrial agree and acknowledge that as

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of the First Amendment Effective Date, IURTC retains ownership of the 3,647 Common Units of Chondrial Therapeutics Holdings, LLC previously granted as partial consideration pursuant to Section 3.6 of the Agreement.

- 2.2. Chondrial assumes all rights, obligations, and liabilities under the Agreement and is bound by all its terms in all respects as of the Effective Date of the Agreement as if it were the original licensee and original party of the Agreement in place of Chondrial Therapeutics IP Holdings, LLC (f/k/a Chondrial Therapeutics, LLC).
- 2.3. Chondrial releases IURTC from all liability and obligations under the Agreement arising before or after the First Amendment Effective Date.
- 2.4. Delete the definition of “Indiana Laboratory” in Section 1 in its entirety and replace with the following:

“Indiana Laboratory” means the laboratory at IU led by Ronald Mark Payne, but excluding any research performed with other principal investigators at IU or pursuant to collaborations with other non-commercial research institutions.
- 2.5. Delete the definition of “Licensed Patents” in Section 1 and replace with the following:

“Licensed Patents” means IU’s rights in:

 - U.S. patent [***];
 - PCT patent application [***];
 - Provisional patent application(s) filed by IU for claims described in IU Case No. [***];
 - With the exception of U.S. patent application [***], all U.S. patent applications claiming priority to the above-referenced patents or applications, including without limitation divisionals, equivalent continuations, and subject matter claimed in continuations-in-part applications that is entitled to the priority filing date of any of the above;
 - Foreign equivalent applications claiming priority to the abovereferenced patents or applications;
 - Patents issuing from any of the above-referenced applications;
 - Any of the foregoing during reissue, re-examination, opposition, or post grant review proceedings;
 - Reissues and re-examinations of any of the above-referenced patents;
 - Any extensions of or supplementary protection certificates referencing any of the above patents, including, without limitation, any regulatory exclusivities (including under 21 C.F.R. §§ 314 and 316) or equivalents thereof; and
 - Other forms of government-issued rights substantially similar to any of the foregoing.

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2.6. Delete the definition of “Option Invention” and replace with the following:

“Option Invention” means any Sponsored Option Invention, Field Option Invention, or Joint Option Invention. “Sponsored Option Invention” means an invention that is invented in the performance of research under the MSRA either (a) solely by IU employees in the Indiana Laboratory or (b) jointly by IU employees in the Indiana Laboratory and Chondrial employees in the Chondrial Laboratory. “Field Option Invention” means an invention that is not a Sponsored Option Invention, but is solely invented by IU employees in the Indiana Laboratory, is invented within three (3) years after the First Amendment Effective Date, disclosed to IU’s technology transfer office, and claims subject matter that is in the Field. “Joint Option Invention” means an invention that is not a Sponsored Option Invention, but is jointly invented by IU employees in the Indiana Laboratory with an obligation to assign patent rights to IU and Chondrial employees in the Chondrial Laboratory with an obligation to assign patent rights to Chondrial, invented within six (6) years after the First Amendment Effective Date, and disclosed to IU’s technology transfer office.

2.7. Add the following definition of “Inventors” at the end of Section 1:

“Inventors” means Ronald Mark Payne, Clifford M. Babbey, Gregory R. Wagner, P. Melanie Pride, and any IU employee that is an inventor of an Option Invention.

2.8. Add the following definition of “MSRA” at the end of Section 1:

“MSRA” means a Master Sponsored Research Agreement signed between IU and Chondrial Therapeutics, Inc., the parent company of Chondrial, to fund research to be performed in the Indiana Laboratory.

2.9. Delete Section 3 and its subsections in their entirety and replace with the following:

3. License Fees, Royalties and other Consideration

3.1 Royalty. In partial consideration for the rights, license and Option granted under this Agreement, Chondrial will pay to IU a royalty of (i) [***] of Net Sales by Chondrial, Affiliates, or Sublicensees in Patent Countries and (ii) [***] of Net Sales by Chondrial, Affiliates, or Sublicensees in Non-Patent Countries.

3.2 Sublicense Fee. In partial consideration for the rights, license and Option granted under this Agreement, Chondrial will pay to IU the following percentages of any and all Sublicense Consideration as described in Section 3.2 below, subject to Section 3.5:

3.2.1 [***] during the period from the Effective Date through

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such time as Chondrial is obligated to pay IU the milestone referred to in Section 3.4 (a); or

3.2.2 *** during the period commencing upon the occurrence of the event referred to in Section 3.2.1 above through such time as Chondrial is obligated to pay IU the milestone referred to in Section 3.4 (b); or

3.2.3 *** during the period commencing upon the occurrence of the event referred to in Section 3.2.2 above and continuing thereafter during the Term.

3.3 For purposes of this Agreement, “Sublicense Consideration” means ***. For the removal of doubt, Sublicense Consideration excludes ***. For the further removal of doubt, to the extent a Sublicense agreement includes the grant of rights unrelated to the rights to the Licensed Patents and unrelated in any way to the Licensed Products, “Sublicense Consideration” will only include a portion of amounts paid by a Sublicensee equal to the proportional value of the Licensed Patents and Licensed Products relative to the value of the other unrelated rights granted to such Sublicensee in such Sublicense agreement.

3.4 Milestones. In partial consideration for the rights, license and Option granted under this Agreement, Chondrial will pay to IU the following amounts upon the achievement of the following events:

(a) Enrollment of the first patient in the first Phase I (or its non-U.S. equivalent) clinical trial of a Licensed Product: ***;

(b) ***: ***;

(c) ***: ***;

(d) ***: ***

3.4.1 The events listed in this Section 3.4 (a)-(d) are intended to be sequential and reflect the presumed path that a Licensed Product will take through the regulatory approval process. If any of these events does not occur for any reason, the fee due upon that skipped event(s) will be due upon the achievement of the subsequent event (and in no event later than the first commercial sale of the first Licensed Product).

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- 3.4.2 Milestones for Patent Issuance. In partial consideration for the rights, license and Option, Chondrial agrees to pay IU the following amounts upon the ***:
- (a) Grant of United States patent: ***. This is increased to a total of *** if issuance occurs before expiration of U.S. Patent No. ***;
 - (b) Grant of European patent: ***;
 - (c) Grant of Canadian patent: ***;
 - (d) Grant of Australian patent: ***; and
 - (e) Grant of Brazilian patent: ***
- 3.5 In the event that Chondrial is required to pay WFUHS Consideration, then Chondrial may deduct sixty percent (60%) of such WFUHS Consideration from the consideration due to IU under Sections 3.1-3.4 provided that if a Valid Claim in the Licensed Patents covering a composition of matter has issued before the first filing deadline for an application for patent term extension of U.S. Patent no. *** (“WFUHS Patents”), then Section 3.5 shall expire on December 17, 2025. If a Valid Claim in the Licensed Patents covering a composition of matter has not issued before the first filing deadline for an application for patent term extension of the WFUHS Patents, then Section 3.5 shall expire upon the expiration of the last to expire WFUHS Patent.
- 3.6 In partial consideration for the rights granted under the option agreement among Chondrial, IURTC, and WFUHS dated February 14, 2014, Chondrial will issue to IURTC 3,647 Common Units of Chondrial Therapeutics Holdings, LLC (“Chondrial Holdings”). In connection with the issuance of the Common Units to IURTC, IURTC will be required to execute an Investors’ Rights Agreement, Right of First Refusal and Co-Sale Agreement, and Amended and Restated Limited Liability Company Agreement, substantially in the forms attached hereto as Exhibits A-C, respectively, which will be executed concurrently with the execution of this Agreement.
- 3.7 In partial consideration for the rights, license and Option granted under this Agreement, Chondrial will pay to IU an issue fee of ten thousand dollars (\$10,000.00 U.S.) within thirty (30) days of the First Amendment Effective Date.

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3.8 In partial consideration for the rights, license and Option granted under this Agreement, Chondrial will pay to IU a minimum annual royalty of five thousand dollars (\$5,000.00 U.S.) starting the 2020 calendar year for the Term of the Agreement. Chondrial must pay the minimum annual royalty for a given calendar year to IU on or before January 31 of such calendar year. The minimum annual royalty for a given calendar year **will** be credited against any royalties due and owing with respect to Net Sales pursuant to Sections 3.1 and 3.5 during the calendar year in which such minimum annual royalty was paid.

2.10. Delete Section 5.2 and its subsections in their entirety and replace with the following:

5.2 Without limiting the generality of the diligence provisions of Section 5.1 above, Chondrial will achieve (either itself or through its Affiliates and/or its Sublicensees) the following milestones by the following dates ("Milestones"):

- (a) Chondrial will have at least two full-time equivalent personnel working on the development, manufacturing and marketing of the Licensed Products within the twelve (12) month period from the Effective Date and each subsequent year thereafter;
- (b) Enrollment of the first patient in the first Phase I (or its non-U.S. equivalent) clinical trial of a Licensed Product by June 30, 2020;
- (c) Enrollment of the first patient in the first Phase II (or its non-U.S. equivalent) clinical trial of a Licensed Product by June 30, 2022.

5.2.1 Chondrial will provide to IU (at the time of the next due report under Section 8) written notice of the achievement of each Milestone in this Section 5.2 (and continued confirmation of Chondrial's sustained achievement of Section 5.2(a)).

5.2.2 Notwithstanding the foregoing, IU shall not unreasonably withhold its assent to any revisions of such Milestones if requested in writing by Chondrial and supported by evidence of continued diligence and/or difficulties or delays that Chondrial could not have reasonably avoided.

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2.11. Delete Section 6 and its subsections in their entirety and replace with the following:

6. Option

- 6.1 When an Option Invention is disclosed to IU, IU will promptly forward a copy to Chondrial, whereupon Chondrial will have the Option Period to exercise the Option to license IU's rights in the Option Invention in accordance with the procedures described in Section 6 herein. Any such disclosure will be considered IU Confidential Information under Section 13. Chondrial must exercise its Option in the Option Invention by notifying IU in writing ("Option Notice").
- 6.2 The Option granted in Section 2.1 expressly does not include the right to practice the Licensed Patents or other intellectual property in any other way not expressly provided for in this Section 6.
- 6.3 Subject to any third party obligations and following IU's receipt of an Option Notice for a Field Option Invention, Joint Option Invention, or Sponsored Option Invention that is related to a TAT-Frataxin fusion protein or the use or manufacture thereof, the parties agree to amend this Agreement in accordance with Section 19.1 to add IU's rights in a Field Option Invention, Joint Option Invention, or Sponsored Option Invention to the definition of Licensed Patents. Chondrial will pay an issue fee of [***] for each Option Invention added to the definition of Licensed Patents pursuant to this Section 6.3 within thirty (30) days of amending the Agreement. For clarity, if Chondrial does not provide an Option Notice within the Option Period, neither party will have any further obligations to the other with respect to the Option Invention and IU's rights in such Option Invention will be disposed of in accordance with IU's policies, with no further obligation to Chondrial.
- 6.4 Subject to any third party obligations and IU's receipt of an Option Notice for any Joint Option Invention or Sponsored Option Invention not encompassed by Section 6.3, Chondrial will be granted a first right to negotiate a license under IU's rights in such Option Invention for a period of [***] from the date that IU originally disclosed such Option Invention to Chondrial ("Negotiation Period"). For clarity, if Chondrial does not provide an Option Notice for the Option Invention within the Option Period or if the parties are unable to execute a license within the Negotiation Period, neither party will have any further obligations to the other with respect to the Option Invention and IU's rights in such Option Invention will be disposed of in accordance with IU's policies, with no further obligation to Chondrial.

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6.5 Any license entered into between Chondrial and IU with respect to any Option Inventions pursuant to Section 6.4 will be negotiated in good faith by the parties.

2.12. Delete Section 9.1 in its entirety and replace with the following:

9.1 IU will prepare, file, prosecute, defend, and maintain the Licensed Patents in its discretion in accordance with the terms and conditions herein. IU will instruct its attorneys to keep Chondrial informed of patent prosecution in the Field and to seek and reasonably accommodate Chondrial's comments and suggestions prior to taking material actions for the same (provided Chondrial is not in breach of this Agreement). Subject to IU's prior written consent, which will not be unreasonably withheld, Chondrial may request for Chondrial's patent counsel to prepare initial drafts of pertinent documents, including applications or office action responses, for review and consideration by IU. Provided Chondrial is not in breach of this Agreement and subject to Section 9.12, IU will not abandon, cease prosecution or reduce the scope of any Licensed Patent without first notifying Chondrial in writing at least sixty (60) days in advance of any filing or maintenance deadline, and Chondrial will have the right, but not obligation, to assume such activities at Chondrial's sole cost and expense.

2.13. Delete Section 9.2 in its entirety and replace with the following:

9.2 IU will authorize Chondrial to communicate directly with IU's patent counsel, and Chondrial will authorize IU to communicate directly with Chondrial's patent counsel. All information exchanged among IU's patent counsel, Chondrial's patent counsel, the parties, and/or the Inventors regarding the preparation, filing, prosecution, issue, defense, or maintenance of the Licensed Patents will be deemed Confidential Information of the disclosing party, whether such disclosure is made by the party itself or by the party's patent counsel. In addition, the parties acknowledge and agree that, with regard to such preparation, filing, prosecution, issue, defense, and maintenance of the Licensed Patents, the interests of the parties as licensor and licensee are to obtain the strongest and broadest patent protection possible, and as such, are aligned and legal in nature. The parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Patents, including without limitation, privilege under the common interest doctrine and similar or related doctrines. The parties also agree and acknowledge that activities undertaken pursuant to this Agreement do not give rise to an attorney-client relationship between a party and the other party's patent counsel.

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2.14. Delete Section 9.4 in its entirety and replace with the following:

9.4 Within fifteen (15) days after the Effective Date, forty-three thousand three hundred seventy-seven dollars and eighty-one cents (\$43,377.81) for expenses incurred prior to the Effective Date for the Licensed Patents. For clarity, the parties confirm that this payment was made before the First Amendment Effective Date and that no further payment pursuant to Section 9.4 is due.

2.15. Delete Section 11.2 in its entirety and replace with the following:

11.2 During the Term, Chondrial will have the first right, but not the obligation, to prosecute at its own expense any such infringements of the Licensed Patents and, upon receipt of IU's written consent, such consent not to be unreasonably withheld, Chondrial may join IU (as appropriate) as a party plaintiff in any such suit, without expense to IU. Similarly, during the Term, Chondrial will have the right to defend at its own expense any declaratory judgment action alleging invalidity or non-infringement of any of the Licensed Patents, and, upon receipt of IU's written consent, such consent not to be unreasonably withheld, Chondrial may join IU (as appropriate) as a party in any such suit, without expense to IU. For clarity, IU agrees to join any action in which it is found to be an indispensable party. The total cost of any such action commenced or defended solely by Chondrial will be borne by Chondrial. Any recovery of damages by Chondrial as a result of such action will be applied first in satisfaction of any reasonable unreimbursed expenses and attorneys' fees of Chondrial relating to the action. The balance remaining from any such recovery will be distributed to Chondrial, provided that Chondrial will pay to IU such royalties as would otherwise be applicable under Section 3.1 hereof for that portion of Chondrial's recovery attributable to lost sales, payments or revenues.

2.16. Delete Section 12.4 and its subsections in their entirety and replace with the following:

12.4 Chondrial, Affiliates extended rights under Section 2.1, and Sublicensees will obtain and maintain commercial general liability insurance with a reputable and financially secure insurance carrier prior to clinical testing, making, using, importing, offering to Sell, or Selling any Licensed Product or engaging in any other act involving any Licensed Product or the Licensed Patents.

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- 12.4.1 The insurance will identify IU Indemnitees as additional insureds and will provide that the carrier will notify IU in writing at least thirty (30) days prior to cancellation, except 10 days for the non-payment of premium.
- 12.4.2 The insurance will include coverage for product liability, contractual liability, clinical trials liability if any such trial is performed, and all other coverages standard for such policies with a minimum of *** per occurrence and *** annual aggregate. Such insurance will additionally include errors and omissions insurance with a minimum of *** per occurrence.
- 12.4.3 Insurance policies purchased to comply with this Section will be kept in force for at least five (5) years after the last Sale of Licensed Product.
- 12.4.4 Chondrial will obtain, keep in force and maintain worker's compensation insurance as legally required in the jurisdiction in which Chondrial is doing business.

2.17. Delete Section 12.5 in its entirety and replace with the following:

- 12.5 At IU's request, Chondrial will provide IU with a certificate of insurance and notices of subsequent renewals for its insurance and that of Affiliates extended rights under Section 2.1 and Sublicensees.

2.18. Delete Section 18 and its subsections in their entirety and replace with the following:

18. Payments, Notices and Other Communications

- 18.1 Any payments made to IU pursuant to this Agreement will be made to the address below or as IU will designate by written notice given to Chondrial:

The Trustees of Indiana University
Attn: Innovation and Commercialization Office
Executive Director, IU Agreement No. 2017-0063
518 Indiana Avenue
Indianapolis, IN 46202

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

- 18.2 Any notice or other communication pursuant to this Agreement will be sufficiently made or given on the date of mailing if sent to such party by email, overnight courier (e.g., Federal Express) or certified first class mail, postage prepaid, addressed to it at its address below or as it will designate by written notice given to the other party:

If to IU:

The Trustees of Indiana University
 Attn: Innovation and Commercialization Office
 Executive Director, IU Agreement No. 2017-0063
 107 S. Indiana Ave., Bryan Hall
 211 Bloomington, IN 47405

With copy to:

The Trustees of Indiana University
 Attn: Innovation and Commercialization Office
 Executive Director, IU Agreement No. 2017-0063
 518 Indiana Avenue
 Indianapolis, IN 46202

Email for patent prosecution: patents@iu.edu
 Email for patent cost reimbursement: licenses@iu.edu
 Email for financial consideration: licenses@iu.edu

If to Chondrial:

Chondrial Therapeutics, Inc.
 150 Monument Rd., Suite 207
 Bala Cynwyd, PA 19004
 Attn: Legal

Email: info@chondrialtherapeutics.com

3. Except as provided in this First Amendment, all other terms and conditions of the Agreement remain unmodified and in full force and effect.
4. In the event that IU has an ownership interest in Provisional Patent Application No. [***], or Provisional Patent Application No. [***], such ownership interest shall be considered an Option Invention that is related to a TAT-Frataxin fusion protein or the use or manufacture thereof and subject to Section 6.3 as amended.
5. This First Amendment may be executed in counterparts, each of which will be deemed an original and all of which when taken together will be deemed one instrument. Facsimile,

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

Portable Document Format (PDF) or photocopied signatures will have the same legal validity as original signatures.

Witness: IU, IURTC, and Chondrial have caused this First Amendment to be executed by their duly authorized representatives as of the First Amendment Effective Date.

The Trustees of Indiana University

By: /s/ Karen White
Name: Karen White
Title: Executive Director, ICO
Date: 8/21/2019

Chondrial Therapeutics IP, LLC

By: /s/ Carole Ben-Maimon
Name: Carole Ben-Maimon
Title: President, CEO
Date: 8/21/2019

Indiana University Research and Technology Corporation

By: /s/ Karen White

Name: Karen White

Title: Executive Director, ICO

Date: 8/21/2019

CERTIFICATION

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

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

Date: August 14, 2020

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

Carole S. Ben-Maimon, M.D.

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, Michael Celano, certify that:

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

Date: August 14, 2020

/s/ Michael Celano

Michael Celano

Chief Financial Officer

(Principal Financial Officer and Accounting Officer)

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

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

- (1) The Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2020

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

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

Date: August 14, 2020

/s/ Michael Celano

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