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

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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

ZAFGEN, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-3857670**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

Zafgen, Inc.
3 Center Plaza, Suite 610
Boston, Massachusetts 02108
(Address of principal executive offices, including zip code)

Registrant's Telephone Number, Including Area Code: (617) 622-4003

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	ZFGN	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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Emerging growth company	☐
Smaller reporting company	☒		

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

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 April 30, 2020, there were 37,469,596 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q Report, or Quarterly Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the accuracy of our estimates regarding expenses, future revenues, cash forecasts and capital requirements;
- our plans and expectations regarding the merger with Chondrial Therapeutics, Inc., including the expected completion of the merger;
- our strategies, goals, prospects, plans, expectations, forecasts or objectives of with Chondrial Therapeutics, Inc. or the combined company;
- the impacts of the current COVID-19 pandemic on our continuing business and operations, the completion of the proposed merger with Chondrial Therapeutics, Inc., and the business and operations of the combined company;
- regulatory and political developments in the United States and foreign countries;
- our ability to obtain additional financing when needed;
- the loss of our executive, financial and strategic alternatives teams;
- potential de-listing from the NASDAQ Global Market; and
- other risks and uncertainties, including those listed under Part I, Item 1A. Risk Factors.

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. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report. 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 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.

Zafgen, Inc.

INDEX

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

ZAFGEN, INC.

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

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 38,980	$ 27,211
Marketable debt securities	24,905	43,050
Tax incentive receivable	214	243
Prepaid expenses and other current assets	581	999
Total current assets	64,680	71,503
Property and equipment, net	743	821
Operating lease right-of-use assets	6,928	7,051
Restricted cash	1,339	1,339
Other assets	12	20
Total assets	$ 73,702	$ 80,734
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 322	$ 632
Accrued expenses	881	1,190
Accrued restructuring costs	981	2,709
Operating lease liabilities, current	410	386
Notes payable, current	7,273	7,273
Total current liabilities	9,867	12,190
Notes payable, long-term	6,747	8,464
Operating lease liabilities	6,346	6,456
Total liabilities	22,960	27,110
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of March 31, 2020 and December 31, 2019; no shares issued and outstanding as of March 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 37,469,596 and 37,446,498 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	37	37
Additional paid-in capital	450,623	449,903
Accumulated deficit	(399,949)	(396,351)
Accumulated other comprehensive income	31	35
Total stockholders' equity	50,742	53,624
Total liabilities and stockholders' equity	$ 73,702	$ 80,734

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

ZAFGEN, INC.

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

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Revenue	$ —	$ —
Operating expenses:		
Research and development	(94)	9,631
General and administrative	3,647	3,646
Restructuring charges	10	—
Total operating expenses	3,563	13,277
Loss from operations	(3,563)	(13,277)
Other income (expense):		
Interest income	258	642
Interest expense	(301)	(500)
Other income	218	—
Foreign currency transaction (losses) gains, net	(210)	23
Total other (expense) income, net	(35)	165
Net loss	$ (3,598)	$ (13,112)
Net loss per share, basic and diluted	$ (0.10)	$ (0.35)
Weighted average common shares outstanding, basic and diluted	37,467,411	37,313,947
Comprehensive loss:		
Net loss	$ (3,598)	$ (13,112)
Other comprehensive (loss) income:		
Unrealized (loss) gain on marketable debt securities	(4)	34
Total other comprehensive (loss) income	(4)	34
Total comprehensive loss	$ (3,602)	$ (13,078)

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

ZAFGEN, INC.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Par Value				
Balances as of December 31, 2019	37,446,498	$ 37	$ 449,903	$ (396,351)	$ 35	$ 53,624
Issuance of common stock upon exercise of stock options and employee stock purchase plan	10,911	—	10	—	—	10
Issuance of restricted stock units	12,187	—	—	—	—	—
Stock-based compensation expense	—	—	710	—	—	710
Unrealized loss on marketable debt securities	—	—	—	—	(4)	(4)
Net loss	—	—	—	(3,598)	—	(3,598)
Balances as of March 31, 2020	37,469,596	$ 37	$ 450,623	$ (399,949)	$ 31	$ 50,742
Balances as of December 31, 2018	37,287,221	$ 37	$ 444,212	$ (350,945)	$ (33)	$ 93,271
Issuance of common stock upon exercise of stock options and employee stock purchase plan	31,391	—	95	—	—	95
Issuance of restricted stock units	4,467	—	—	—	—	—
Stock-based compensation expense	—	—	2,076	—	—	2,076
Unrealized gain on marketable debt securities	—	—	—	—	34	34
Net loss	—	—	—	(13,112)	—	(13,112)
Balances as of March 31, 2019	37,323,079	$ 37	$ 446,383	$ (364,057)	$ 1	$ 82,364

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

ZAFGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Cash flows from operating activities:		
Net loss	$ (3,598)	$ (13,112)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	710	2,076
Depreciation expense	76	51
Loss on disposal of fixed assets	2	—
Unrealized foreign currency transaction losses (gains)	29	(14)
Amortization of discount on marketable debt securities	(52)	(283)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	418	469
Tax incentive receivable	—	(94)
Accounts payable	(310)	(445)
Accrued restructuring costs	(1,728)	—
Accrued expenses	(163)	(1,119)
Net cash used in operating activities	(4,616)	(12,471)
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable debt securities	20,532	34,275
Purchases of marketable debt securities	(2,339)	(33,466)
Purchases of property and equipment	—	(2)
Net cash provided by investing activities	18,193	807
Cash flows from financing activities:		
Repayment of notes payable	(1,818)	—
Proceeds from exercise of common stock options and employee stock purchase plan	10	95
Net cash (used in) provided by financing activities	(1,808)	95
Net increase (decrease) in cash, cash equivalents and restricted cash	11,769	(11,569)
Cash, cash equivalents and restricted cash at beginning of period	28,550	49,331
Cash, cash equivalents and restricted cash at end of period	$ 40,319	$ 37,762
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment included in accounts payable	$ —	$ 11
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 212	$ 339

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Zafgen, Inc., or the Company, was incorporated on November 22, 2005 under the laws of the State of Delaware. The Company is a biopharmaceutical company that has leveraged its proprietary knowledge of the methionine aminopeptidase 2 (“MetAP2”) pathway to pioneer the study of MetAP2 inhibitors in both common and rare metabolic disorders.

Following an extensive process of evaluating strategic alternatives for the Company and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on December 17, 2019, the Company entered into an Agreement and Plan of Merger, or the Merger Agreement, with Chondrial Therapeutics, Inc., or Chondrial, pursuant to which a wholly owned subsidiary of the Company will merge with and into Chondrial, with Chondrial continuing as the surviving corporation of the merger and a wholly owned subsidiary of the Company, or the merger. Under the exchange ratio formula in the Merger Agreement, as of immediately after the merger, the former Chondrial securityholders are expected to own approximately 60% of the outstanding shares of the Company’s common stock on a fully-diluted basis and the Company’s stockholders as of immediately prior to the merger are expected to own approximately 40% of the outstanding shares of the Company’s common stock on a fully-diluted basis. The relative percentage ownership of the combined company was derived using a stipulated value of Chondrial of approximately $67.5 million and of the Company of approximately $45.0 million. The Company’s valuation was determined based on a projected net cash, cash equivalents and marketable securities balance minus outstanding liabilities, as defined in the Merger Agreement, of $40.0 million as of a determination date prior to the closing of the merger, but subject to adjustment as described below, plus an additional $5.0 million of enterprise value. If the Company’s actual net cash is between $39.5 million and $40.5 million, no adjustment will be made to the ownership percentages based on the Company’s net cash. The Company’s target net cash, lower target net cash and upper target net cash amounts will be reduced by $21,311 per day beginning on March 31, 2020 through the closing date of the merger, and the Chondrial valuation will be increased by $111,656 per day beginning on March 31, 2020 through the closing date of the merger, resulting in a corresponding adjustment to the exchange ratio and an increase to the ownership percentage of Chondrial’s stockholder in the combined company.

The Merger Agreement provides the Company and Chondrial with specified termination rights, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of $3,375,000. In addition, in connection with certain terminations of the Merger Agreement, either party may be required to pay the other party’s third party expenses up to $350,000. In connection with the merger, the Company will seek to amend its certificate of incorporation to: (i) effect a reverse split of the Company’s common stock at a ratio to be determined by the Company and Chondrial, which is intended to ensure that the listing requirements of the Nasdaq Global Market are satisfied and (ii) change the name of Zafgen, Inc. to “Larimar Therapeutics, Inc.”

The Company’s and Chondrial’s obligations to consummate the merger are subject to the satisfaction or waiver of customary closing conditions, including, among others, obtaining the requisite approvals of the Company’s stockholders and satisfaction of minimum net cash thresholds of $30,000,000 by the Company and not less than zero by Chondrial. The sole stockholder of Chondrial has approved the Merger Agreement. In connection with the execution of the Merger Agreement, the Company entered into stockholder support agreements with its current directors and certain officers and the Company’s largest stockholder, which collectively beneficially own or control an aggregate of approximately 9.7% of its outstanding shares of common stock. Each of the stockholders party to such stockholder support agreements has agreed to vote or cause to be voted, all of the shares of the Company’s common stock beneficially owned by such stockholder in favor of the stockholder proposals submitted at the Company’s stockholders meeting to be held in connection with the merger.

The Company expects to devote significant time and resources to the completion of the merger with Chondrial. However, there can be no assurance that such activities will result in the completion of the merger. Further, the completion of the merger ultimately may not deliver the anticipated benefits or enhance shareholder value.

The Company has incurred losses and negative cash flows from operations since its inception. As of March 31, 2020, the Company had an accumulated deficit of $399.9 million. From its inception through March 31, 2020, the Company received net proceeds of $397.9 million from the sales of redeemable convertible preferred stock, the issuance of convertible promissory notes, the proceeds from its initial public offering (“IPO”) in June 2014 and its follow-on offerings in January 2015 and July 2018. On July 2, 2018, the Company completed a public offering of its common stock, which resulted in the sale of 9,200,000 shares at a price of $7.50 per share, resulting in net proceeds of approximately $64.6 million after deducting underwriting discounts and commissions, as well as offering costs. As disclosed in Note 5 to the condensed consolidated financial statements, the Company has a term loan with an aggregate principal balance of $12.7 million as of March 31, 2020 The loan agreement requires that the Company maintain certain minimum liquidity at all times, which as of March 31, 2020 was approximately $13.4 million. If the minimum liquidity covenant is not met, the Company may be required to repay the loan prior to scheduled maturity dates. The Term Loan also includes events of default, the occurrence and continuation of any of which provides the lenders the right to exercise remedies against the Company and the collateral securing the amounts due under the Term Loan. These events of default include, among other things, failure to pay any amounts due under the Term Loan, insolvency, the occurrence of a material adverse event, the occurrence of any default under certain other indebtedness and a final judgment against the Company in an amount greater than $0.3 million. During the quarter ended March 31, 2020 the Company was in compliance with all covenants under the term loan. The Company has estimated that the risk of subjective acceleration under the Term Loan’s material adverse events clause is reasonably possible, however not probable and therefore has classified the outstanding principal balance in current and long-term liabilities based on contractually scheduled principal payments. However, the assessment of such probability of the debt holder calling the debt is subjective and their actions and/or the Company’s related assessment could change in the future, which in turn would impact the classification of the debt balances.

Based on its current operating plans, the Company believes its cash, cash equivalents and marketable debt securities of $63.9 million as of March 31, 2020, will be sufficient to fund its anticipated level of operations, capital expenditures and satisfy debt repayments for a period of at least 12 months from the date of this Quarterly Report. Until such time, if ever, as the Company can generate substantial product revenue, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other sources of funding. The Company expects to generate operating losses for the foreseeable future. If the Company is unable to raise additional funds through equity or debt financings, the Company may be required to delay, limit, reduce or terminate future product development or future commercialization efforts or grant rights to develop and market products or product candidates that the Company would otherwise prefer to develop and market ourselves.

On April 21, 2020, the Company received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying it that, for the last 30 consecutive business days, the bid price for the Company’s common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market, referred to as the minimum bid price rule. In accordance with Nasdaq Listing Rules, the Company has an initial period of 180 calendar days. On April 16, 2020, Nasdaq announced it was providing temporary relief from continued listing bid price requirements through June 30, 2020. Under the relief the Company will have additional time to regain compliance with the listing bid price requirements with the compliance period beginning July 1, 2020. As such, the compliance period for the Company will expire on December 28, 2020. The Company is actively monitoring its stock price and will consider any and all options available to the Company to maintain compliance. The alternatives to trading on the Nasdaq Capital Market or another national securities exchange are generally considered to be less efficient and less broad-based than the national securities exchanges and the liquidity of the Company’s common stock will likely be reduced if we fail to regain compliance with the minimum bid price rule.

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries Zafgen Securities Corporation, Zafgen Australia Pty Limited, Zafgen Animal Health, LLC, and Zordich Merger Sub, Inc. All intercompany balances and transactions have been eliminated.

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 accounting principles generally accepted in the United States of America (“GAAP”). The accompanying unaudited condensed consolidated financial statements as of March 31, 2020 and for the three months ended March 31, 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 Annual Report on Form 10-K, for the year ended December 31, 2019, on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company’s condensed consolidated financial position as of March 31, 2020 and condensed consolidated results of operations and cash flows for the three months ended March 31, 2020 and 2019 have been made. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

2. Summary of Significant Accounting Policies

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, the disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company’s estimates.

Marketable debt securities

Marketable debt securities consist of debt investments with original maturities greater than ninety days. The Company has classified its debt investments with maturities beyond one year as short term, based on their highly liquid nature and because such marketable debt securities represent the investment of cash that is available for current operations. 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.

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. 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 March 31, 2020 and 2019, from the computation of diluted net loss per share for the three months ended March 31, 2020 and 2019 because they had an anti-dilutive impact due to the net loss incurred for the periods:

	As of March 31,	
	2020	2019
Options to purchase common stock	3,945,647	6,663,162
Unvested restricted common stock	40,766	351,371
	3,986,413	7,014,533

Risks and Uncertainties

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on the Company's business is highly uncertain and difficult to predict, as the response to the pandemic is in its incipient stages and information is rapidly evolving. Capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is possible that it could cause a local and/or global economic recession. Such economic disruption could have a material adverse effect on the Company's business. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The magnitude and overall effectiveness of these actions remains uncertain.

The severity of the impact of the COVID-19 pandemic on the Company's business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic, all of which are uncertain and cannot be predicted. The Company is required to have a net cash balance of at least $30,000,000 at the closing of the merger as a condition to Chondrial's obligation to consummate the merger. For purposes of the merger agreement, net cash is subject to certain reductions, including, without limitation, accounts payable, accrued expenses (except those related to the merger), current liabilities payable in cash, unpaid expenses related to the merger and certain other unpaid obligations, including outstanding lease obligations. The liability with regards to the Company's outstanding lease obligations is a large component of the Company's net cash and COVID-19 has created uncertainties surrounding our ability to take the steps necessary to sublease or negotiate a buy-out of our existing leases. In the event that the Company's net cash falls below this threshold, a condition to the Chondrial's obligation to consummate the merger will fail to be satisfied and Chondrial will have the right to terminate the merger agreement at an outside date of September 17, 2020 (subject to extension as provided in the merger agreement) if the Company's net cash continues to be lower than the $30,000,000 threshold. As of the date of issuance of these condensed consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact the Company's financial condition, liquidity, or results of operations is uncertain.

Recently Issued and Adopted Accounting Pronouncements

In June 2016 the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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, which have the same effective date and transition date of January 1, 2020. 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.

This standard became effective for the Company on January 1, 2020, and based on the composition of the Company's marketable debt securities, current economic conditions and historical credit loss activity, 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. Fair Value Measurements and Marketable Debt Securities

Fair Value Measurements

The following tables present information about the Company's financial assets that have been measured at fair value as of March 31, 2020 and December 31, 2019 and indicate the fair value of the hierarchy of the valuation inputs utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair value determined by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices, for similar assets or liabilities, quoted market prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

The following tables summarize the Company's cash equivalents and marketable debt securities as of March 31, 2020 and December 31, 2019:

	March 31, 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	$ 35,865	$ 35,865	$ —	$ —
Total cash equivalents	35,865	35,865	—	—
Marketable debt securities:				
U.S. government securities	10,629	—	10,629	—
Corporate bonds	8,589	—	8,589	—
Commercial paper	5,687	—	5,687	—
Total marketable debt securities	24,905	—	24,905	—
Total cash equivalents and marketable debt securities	$ 60,770	$ 35,865	$ 24,905	$ —

	December 31, 2019			
	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	$ 18,289	$ 18,289	$ —	$ —
U.S. Government securities	3,098	—	3,098	—
Commercial paper	1,047	—	1,047	—
Total cash equivalents	22,434	18,289	4,145	—
Marketable debt securities:				
U.S. Government securities	14,996	—	14,996	—
Corporate bonds	14,648	—	14,648	—
Commercial paper	13,406	—	13,406	—
Total marketable debt securities	43,050	—	43,050	—
Total cash equivalents and marketable debt securities	$ 65,484	$ 18,289	$ 47,195	$ —

The carrying amounts reflected in the condensed consolidated balance sheets for tax incentive receivable, accounts payable, and accrued expenses approximate fair value due to their short-term maturities. The carrying value of the Company's outstanding notes payable approximates fair value (a Level 2 fair value measurement), reflecting interest rates currently available to the Company.

Marketable Debt Securities

The following tables summarize the Company's marketable debt securities as of March 31, 2020 and December 31, 2019:

	March 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Assets:				
U.S. government securities (due within 1 year)	$ 10,596	$ 33	$ —	$ 10,629
Corporate bonds (due within 1 year)	8,590	3	(4)	8,589
Commercial paper (due within 1 year)	5,687	—	—	5,687
	$ 24,873	$ 36	$ (4)	$ 24,905

As of March 31, 2020, the Company did not have an allowance for credit losses.

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Assets:				
U.S. Government securities (due within 1 year)	$ 14,981	$ 15	$ —	$ 14,996
Corporate bonds (due within 1 year)	14,628	20	—	14,648
Commercial paper (due within 1 year)	13,406	—	—	13,406
	$ 43,015	$ 35	$ —	$ 43,050

4. Accrued Expenses

Accrued expenses consisted of the following as of March 31, 2020 and December 31, 2019:

	March 31, 2020	December 31, 2019
	(in thousands)	
Accrued payroll and related expenses	$ 193	$ 37
Accrued professional fees	452	864
Accrued other	236	289
	$ 881	$ 1,190

5. Notes Payable

On December 29, 2017, the Company entered into a loan and security agreement with Silicon Valley Bank (the “Term Loan”). The Term Loan provided for borrowings of $20.0 million. On December 29, 2017, the Company received proceeds of $20.0 million from the issuance of a promissory note. The promissory note issued under the Term Loan is collateralized by substantially all of the Company’s personal property, other than its intellectual property.

Upon entering into the Term Loan, the Company became obligated to make monthly, interest-only payments until March 29, 2019 and, thereafter, to pay 33 consecutive, equal monthly installments of principal and interest from April 1, 2019 through December 1, 2021. The outstanding Term Loan bears a variable interest at an annual rate of 1.25% above the prime rate, which at March 31, 2020 was 3.25%. In addition, a final payment equal to 8.0% of the Term Loan is due upon the earlier of the maturity date, acceleration of the Term Loan or prepayment of all or part of the Term Loan. The Company accrues the final payment amount of $1.6 million, to outstanding debt by charges to interest expense using the effective-interest method from the date of issuance through the maturity date.

Additionally, the Company, as borrower, is required to maintain a minimum cash, cash equivalents and marketable debt securities balance at Silicon Valley Bank of no less than 105% of the total outstanding principal balance of the Term Loan, which was $13.4 million as of March 31, 2020 and $15.3 million as of December 31, 2019.

Further, since 45 days after the Term Loan was entered in, the Company has met its obligation to maintain a balance of unrestricted cash, cash equivalents and marketable debt securities at Silicon Valley Bank in an amount not less than the greater of (i) $55.0 million and (ii) sixty-five percent (65%) of all the Company’s cash, cash equivalents and marketable Debt securities. If the Company does not meet this requirement it will not be considered an event of default provided it immediately secures 87.5% of the principal balance in a restricted cash account.

There are negative covenants restricting the Company’s activities, including limitations on dispositions, mergers or acquisitions; encumbering or granting a security interest in its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; limiting the aggregate value of cash maintained by its Australian subsidiary not to exceed $4.0 million and certain other business transactions.

The Term Loan also includes events of default, the occurrence and continuation of any of which provides the lenders the right to exercise remedies against the Company and the collateral securing the amounts due under the Term Loan, including cash in the amount of the outstanding balance. These events of default include, among other things, failure to pay any amounts due under the Term Loan, insolvency, the occurrence of a material adverse event, the occurrence of any default under certain other indebtedness and a final judgment against the Company in an amount greater than $0.3 million.

As of March 31, 2020 and December 31, 2019, notes payable consist of the following:

	March 31, 2020	December 31, 2019
	(in thousands)	
Notes payable	$ 12,728	$ 14,545
Less: current portion	(7,273)	(7,273)
Notes payable, net of current portion	5,455	7,272
Accretion related to final payment	1,292	1,192
Notes payable, long term	$ 6,747	$ 8,464

During the three months ended March 31, 2020 and 2019, the Company recognized $0.3 million and $0.5 million of interest expense, respectively, related to the Term Loan. The effective annual interest rate as of March 31, 2020 on the outstanding debt under the Term Loan was approximately 7.7%.

6. Stock-Based Awards

The Company's 2014 Stock Option and Incentive Plan, as amended (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 of directors and consultants of the Company. The Company has outstanding stock-based awards under its Amended and Restated 2006 Stock Option Plan but is no longer granting awards under this plan. The Company also issues common stock under its 2014 Employee Stock Purchase Plan (the "ESPP"). As of March 31, 2020, 6,795,572 shares are available for grant under the 2014 Plan, including 1,497,859 shares automatically added to the 2014 Plan on January 1, 2020, and 58,611 shares are available for issuance to participating employees under the ESPP.

The Company recorded stock-based compensation expense related to stock options, restricted common stock and the ESPP in the following expense categories within its condensed consolidated statements of operations for the three months ended March 31, 2020 and 2019 as follows:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Research and development	$ (144)	$ 960
General and administrative	854	1,116
	$ 710	$ 2,076

The Company recorded negative research and development expenses during the three months ended March 31, 2020, which was the result of the reversal of related stock compensation expense related to the termination of the Company's final research and development employee in the first quarter of 2020.

7. Commitments and Contingencies

Leases

On February 12, 2019, the Company entered into a lease with Shigo Center Plaza Owners, LLC, for approximately 17,705 square feet of office space for a new headquarters located at 3 Center Plaza, Boston, Massachusetts. The lease has a term of 124 months with 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. Under the lease agreement, the Company began paying monthly rent beginning four months after the lease commencement, which was June 21, 2019, with total lease payments over the initial term of $10.7 million. During the fourth quarter of 2019 and in conjunction with entering into the Merger Agreement with Chondrial, the Company performed an impairment review of the Company's headquarters lease and related assets and determined that an impairment had not occurred as the estimated fair value of the asset exceeded the carrying value. In addition, due to the continued impact of the COVID-19 pandemic, the Company updated its impairment review as of March 31, 2020 and determined that an impairment had not occurred.

In October 2015, the Company entered into an operating lease for office space in San Diego, California, effective as of October 1, 2015, with a term extended to expire on December 31, 2024.

The future minimum lease payments for the next five years and thereafter as of March 31, 2020, are as follows:

Year Ending December 31, (in thousands)	Operating Leases
2020 (April - December)	824
2021	1,120
2022	1,143
2023	1,165
2024	1,189
Thereafter	5,396
Total lease payments	10,837
Less: imputed interest	(4,081)
Present value of lease liabilities	$ 6,756

During the three months ended March 31, 2020 the Company did not incur any lease expense associated with research and development activities, and the Company incurred $0.3 million of lease expense associated with general and administrative activities. During the three months ended March 31, 2019 the Company incurred $0.1 million of lease expense associated with research and development activities and less than $0.1 million of lease expense associated with general and administrative activities. The components of lease expense are as follows:

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
	(in thousands)	
Operating lease cost	$ 331	$ 127
Short-term lease cost	—	41
Sublease income	(28)	(28)
Total lease cost	$ 303	$ 140

The weighted average remaining lease term and weighted average discount rate of our operating leases are as follows:

	As of March 31, 2020	As of December 31, 2019
Weighted average remaining lease term in years	9.24	9.49
Weighted average discount rate	11.1%	11.1%

Cash paid for amounts included in the measurement of operating lease liabilities was $0.3 million and $0.1 million during the three months ended March 31, 2020 and 2019, respectively, and is included in operating activities within the condensed consolidated statements of cash flows. There were no additional right-of-use assets recognized as non-cash asset additions that resulted from new operating lease liabilities during the three months ended March 31, 2020 or 2019.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its management team and its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2020.

Legal Proceedings

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities would be recorded in the period in which such determination is made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

The Company may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which the Company is focused. The Company is not aware of any material claims as of March 31, 2020.

8. Retirement Plan

Effective January 1, 2018, the Company adopted a 401(k) plan for its employees. Under the terms of the plan, the Company contributes 3% of an employee's annual base salary, up to a maximum of the annual Internal Revenue Service compensation limits, for all full-time employees.

During the three months ended March 31, 2020 and 2019, the Company recognized less than $0.1 million and $0.1 million, respectively, of expense related to its contributions to the 401(k) plan.

9. Australia Research and Development Tax Incentive

The Company's wholly owned subsidiary, Zafgen Australia Pty Limited, which conducts core research and development activities on behalf of the Company, is eligible to receive a 43.5% refundable tax incentive for qualified research and development activities. For the three months ended March 31, 2019, $0.1 million was recorded as a reduction to research and development expenses in the condensed consolidated statements of operations. This amount represented 43.5% of the Company's qualified research and development spending in Australia. For the three months ended March 31, 2020, the Company did not have qualified research and development expenses. The refund is denominated in Australian dollars and, therefore, the related receivable is re-measured into U.S. dollars as of each reporting date. For the three months ended March 31, 2020 and 2019, the Company recorded in its condensed consolidated statements of operations unrealized foreign currency exchange losses of $0.2 million and gains of less than $0.1 million, respectively, related to this tax incentive receivable. As of March 31, 2020 and December 31, 2019, the Company's tax incentive receivable from the Australian government was $0.2 million.

10. Restructuring

In September 2019, the Company's Board of Directors approved a restructuring plan to reduce operating costs and better align the Company's workforce with the needs of its business following the Company's September 5, 2019 announcement regarding the low probability of resolving the clinical hold of ZGN-1061 in the near-term and that the Company will be seeking strategic alternatives.

Under the restructuring plan and a previously announced July 2019 restructuring, the Company reduced its workforce by 20 employees and closed its office in San Diego, California. Affected employees are eligible to receive severance payments and outplacement services in connection with the reduction. In the three months ended March 31, 2020, the Company recorded aggregate restructuring charges of less than $0.1 million related to other employee-related costs. The Company does not expect to incur any additional significant costs associated with these restructurings. During the three months ended March 31, 2020, $1.7 million of the estimated restructuring charges were paid. The Company expects the remaining accrued restructuring costs of $1.0 million will be paid in the next 12 months.

The following table shows the total amount expected to be incurred and the liability related to the 2019 restructuring as of March 31, 2020:

	One-Time Employee Termination Benefits	Contract Termination Costs	Total Expenses
		(in thousands)	
Accrued restructuring costs as of December 31, 2019	$ 2,706	$ 3	$ 2,709
Restructuring charges incurred during the period	10	—	10
Amounts paid during the period	(1,735)	(3)	(1,738)
Accrued restructuring costs as of March 31, 2020	$ 981	$ —	$ 981

The following table summarizes the restructuring charges by category for the period ending March 31, 2020:

	Three Months Ended March 31, 2020 (in thousands)		
	Cash	Non-Cash	Total
Research and development	$ 10	$ —	$ 10
General and administrative	—	—	—
	$ 10	$ —	$ 10

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 Annual Report on Form 10-K for the year ended December 31, 2019, or Annual Report. 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 and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report and in our Annual Report, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report, including those risks identified under the "Risk Factors" section and in our Annual Report.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a biopharmaceutical company that has leveraged our proprietary methionine aminopeptidase 2, or MetAP2, biology platform to pioneer the study of MetAP2 inhibitors in both common and rare metabolic disorders.

Following an extensive process of evaluating strategic alternatives for us and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on December 17, 2019, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Chondrial Therapeutics, Inc., or Chondrial, pursuant to which a wholly owned subsidiary of Zafgen will merge with and into Chondrial, with Chondrial continuing as the surviving corporation and a wholly owned subsidiary of Zafgen and the combined publicly traded, clinical-stage biopharmaceutical company will operate under a new name, Larimar Therapeutics, Inc., or the merger. Under the exchange ratio formula in the Merger Agreement, as of immediately after the merger, the former Chondrial securityholders are expected to own approximately 60% of the outstanding shares of our common stock on a fully-diluted basis and our stockholders as of immediately prior to the merger are expected to own approximately 40% of the outstanding shares of our common stock on a fully-diluted basis. The relative percentage ownership of the combined company was derived using a stipulated value of Chondrial of approximately $67.5 million and of Zafgen of approximately $45.0 million. Our valuation was determined based on a projected net cash, cash equivalents and marketable securities balance minus outstanding liabilities, as defined in the Merger Agreement, of $40.0 million as of a determination date prior to the closing of the merger, but subject to adjustment as described below, plus an additional $5.0 million of enterprise value. If our actual net cash is between $39.5 million and $40.5 million, no adjustment will be made to the ownership percentages based on our net cash. The Company's target net cash, lower target net cash and upper target net cash amounts will be reduced by $21,311 per day beginning on March 31, 2020 through the closing date of the merger, and the Chondrial valuation will be increased by $111,656 per day beginning on March 31, 2020 through the closing date of the merger, resulting in a corresponding adjustment to the exchange ratio and an increase to the ownership percentage of Chondrial's stockholder in the combined company.

The Merger Agreement provides each of us and Chondrial with specified termination rights, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of $3,375,000. In addition, in connection with certain terminations of the Merger Agreement, either party may be required to pay the other party's third party expenses up to $350,000. In connection with the merger, we will seek to amend our certificate of incorporation to: (i) effect a reverse split of our common stock at a ratio to be determined by us and Chondrial, which is intended to ensure that the listing requirements of the Nasdaq Global Market are satisfied and (ii) change the name of Zafgen to "Larimar Therapeutics, Inc."

Our and Chondrial's obligations to consummate the merger are subject to the satisfaction or waiver of customary closing conditions, including, among others, obtaining the requisite approvals of our stockholders and satisfaction of minimum net cash thresholds of $30,000,000 by us and not less than zero by Chondrial. The sole stockholder of Chondrial has approved the Merger Agreement. In connection with the execution of the Merger Agreement, we entered into stockholder support agreements with our current directors and certain officers and our largest stockholder, which collectively beneficially own or control an aggregate of approximately 9.7% of our outstanding shares of common stock. Each of the stockholders party to such stockholder support agreements has agreed to vote or cause to be voted, all of the shares of our common stock beneficially owned by such stockholder in favor of the stockholder proposals submitted at our stockholders meeting to be held in connection with the merger.

We expect to devote significant time and resources to completion of this proposed transaction, which we refer to as the Merger. However, there can be no assurance that such activities will result in the completion of the Merger. Further, the completion of the Merger ultimately may not deliver the anticipated benefits or enhance shareholder value.

We have incurred losses and negative cash flows from operations since our inception. As of March 31, 2020, we had an accumulated deficit of $399.9 million. From our inception through March 31, 2020, we have received net proceeds of $397.9 million from the sales of redeemable convertible preferred stock, the issuance of convertible promissory notes, the proceeds from our initial public offering, or IPO, in June 2014 and our follow-on offerings in January 2015 and July 2018. On July 2, 2018, we completed a public offering of its common stock, which resulted in the sale of 9,200,000 shares at a price of $7.50 per share, resulting in net proceeds of approximately $64.6 million after deducting underwriting discounts and commissions, as well as offering costs. We have a term loan with an aggregate principal balance of $12.7 million as of December 31, 2019. The loan agreement requires us to maintain certain minimum liquidity at all times, which as of March 31, 2020, was approximately $13.4 million. If the minimum liquidity covenant is not met, we may be required to repay the loan prior to scheduled maturity dates. The Term Loan also includes events of default, the occurrence and continuation of any of which provides the lenders the right to exercise remedies against us and the collateral securing the amounts due under the Term Loan. These events of default include, among other things, failure to pay any amounts due under the Term Loan, insolvency, the occurrence of a material adverse event, the occurrence of any default under certain other indebtedness and a final judgment against us in an amount greater than $0.3 million. We have estimated that the risk of subjective acceleration under the material adverse events clause is reasonably possible, however not probable and therefore have classified the outstanding principal in current and long-term liabilities based on contractually scheduled principal payments. However, the assessment of such probability of the debt holder calling the debt is subjective and their actions and/or our related assessment could change in the future, which in turn would impact the classification of the debt balances.

Based on our current operating plans, we believe our cash, cash equivalents and marketable debt securities of $63.9 million as of March 31, 2020 will be sufficient to fund our anticipated level of operations, capital expenditures and satisfy debt repayments for a period of at least 12 months from the issuance date of this Quarterly Report. Until such time, if ever, we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other sources of funding. We expect to generate operating losses for the foreseeable future. If we are unable to raise additional funds through equity or debt financings, we may be required to delay, limit, reduce or terminate product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market itself.

We expect that our existing cash, cash equivalents and marketable debt securities as of March 31, 2020 will enable us to fund our operating expenses, capital expenditure requirements and minimum liquidity requirements associated with our debt facility for a period of at least one year from the issuance date of this Quarterly Report. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

We have not generated any revenue from product sales since our inception, and do not expect to generate any revenue from the sale of products in the near 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 previously consisted of costs associated with our product research and development efforts, which are expensed as incurred. Research and development expenses consisted primarily of:

- personnel costs, including salaries, related benefits and stock-based compensation 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.

Based on the preliminary results from the ZGN-1061 *in vivo* study, we announced that we believe there is a low probability of resolving the clinical hold on ZGN-1061 in the near-term. Subsequently, all further development activities of MetAP2 inhibitors were halted and we withdrew the IND for ZGN-1061 in September 2019.

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, business and corporate development, merger related costs 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.

Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash equivalents and marketable debt securities. Our interest income has not been significant due to low interest earned on invested balances. Our interest income increased following the July 2, 2018 public offering of our common stock and we anticipate that it will subsequently decrease as we continue to incur operating losses.

Interest expense. Interest expense during the three months ended March 31, 2020 and 2019 relates to the loan and security agreement with Silicon Valley Bank, or the Term Loan, of $20.0 million, which closed on December 29, 2017. It bears a variable interest at an annual rate of 1.25% above the prime rate, as well as a final payment equal to 8.0% of the Term Loan, which is being recorded as interest expense over the term through the maturity date using the effective-interest method.

Other income. During the three months ended March 31, 2020, other income consisted of the sale of raw materials that were utilized in the production of our former lead product candidates and the resolution of a dispute with a former third-party vendor.

Foreign currency (losses) gains, net. Foreign currency transaction (losses) gains, net consists of the realized and unrealized gains and losses from foreign currency-denominated cash balances, vendor payables and tax-related receivables from the Australian government. We currently do not engage in hedging activities related to our foreign currency-denominated receivables and payables; as such, we cannot predict the impact of future foreign currency transaction gains and losses on our operating results. See "—Quantitative and Qualitative Disclosures about Market Risk."

Income Taxes

Since our inception in 2005, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2019, we had net operating loss carryforwards that expire for federal and state income tax purposes of $55.7 million and $57.0 million, respectively, which begin to expire in 2026 and 2030, respectively. As of December 31, 2019, we had net operating loss carryforwards that were generated after December 31, 2017, of $21.2 million that do not expire. As of December 31, 2019, we also had available tax credit carryforwards for federal and state income tax purposes of $17.9 million and $4.2 million, respectively, which begin to expire in 2026 and 2022, respectively.

Results of Operations

Comparison of three months ended March 31, 2020 and 2019

The following table summarizes our results of operations for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,		
	2020	2019	Increase (Decrease)
		(in thousands)	
Statement of Operations Data:			
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	(94)	9,631	(9,725)
General and administrative	3,647	3,646	1
Restructuring charges	10	—	10
Total operating expenses	3,563	13,277	(9,714)
Loss from operations	(3,563)	(13,277)	9,714
Other income (expense):			
Interest income	258	642	(384)
Interest expense	(301)	(500)	199
Other income	218	—	218
Foreign currency transaction (losses) gains, net	(210)	23	(233)
Total other (expense) income, net	(35)	165	(200)
Net loss	$ (3,598)	$ (13,112)	$ 9,514

Research and development expenses

	Three Months Ended March 31,		
	2020	2019	Increase (Decrease)
	(in thousands)		
Direct research and development expenses by program:			
MetAP2 inhibitors	$ —	$ 4,990	$ (4,990)
Unallocated expenses:			
Personnel related	40	2,486	(2,446)
Non-cash stock-based compensation	(144)	959	(1,103)
Consultants	—	691	(691)
Other	10	505	(495)
Subtotal	(94)	4,641	(4,735)
Total research and development expenses	$ (94)	$ 9,631	$ (9,725)

Research and development expenses for the three months ended March 31, 2020 decreased $9.7 million compared to the three months ended March 31, 2019. The decrease was primarily due to decreased costs of $5.0 million associated with discontinuation of our MetAP2 program as well as a decrease in our unallocated expenses of $4.7 million. The decrease in unallocated expenses was primarily due to a $2.4 million decrease in personnel related costs and a $1.1 million decrease in non-cash stock-based compensation costs due to the reduction in force in the second half of 2019 and the departure of our last research and development employee during the three months ended March 31, 2020. In addition, unallocated expenses decreased due to a $0.7 million decrease in consultants and $0.5 million decrease in other costs, which was the result of the discontinuation of our MetAP2 program in September 2019. There was negative research and development expenses for the three months ended March 31, 2020 primarily as a result of negative stock-compensation expenses related to the reversal of stock compensation expense associated with the termination of our final research and development employee in the first quarter of 2020.

General and administrative expenses

	Three Months Ended March 31,		
	2020	2019	Increase (Decrease)
	(in thousands)		
Personnel related	$ 723	$ 927	$ (204)
Non-cash stock-based compensation	854	1,116	(262)
Professional fees	1,176	1,097	79
Other	894	506	388
Total general and administrative expenses	$ 3,647	$ 3,646	$ 1

General and administrative expenses for the three months ended March 31, 2020 remained consistent with the three months ended March 31, 2019. Other costs increased by $0.4 million and professional fees increased $0.1 million, as compared to the three months ended March 31, 2019. The increases were the result of merger related costs, increased insurance costs associated with our director and officer insurance and increased facility rental costs. These increases were offset by a decrease of $0.2 million in personnel related costs and a decrease of $0.3 million in non-cash stock-based compensation costs, as compared to the three months ended March 31, 2019, primarily due to the reduction in force in the second half of 2019.

Other (expense) income, net

Interest expense. Interest expense for the three months ended March 31, 2020 and 2019 was $0.3 million and $0.5 million, respectively. The interest expense for the three months ended March 31, 2020 and 2019 is primarily due to the Term Loan of $20.0 million, which closed on December 29, 2017. The Term Loan has a variable annual interest rate of 1.25% above the prime rate, as well as a final payment equal to 8.0% of the Term Loan, which is recorded as interest expense over the term of the loan through the maturity date using the effective-interest method.

Interest income. Interest income of $0.3 million and $0.6 million for the three months ended March 31, 2020 and 2019, respectively, was related to interest earned on our marketable debt securities balances.

Other income. During the three months ended March 31, 2020, other income of $0.2 million consisted of the sale of raw materials that were utilized in the production of our former lead product candidates and the resolution of a dispute with a former third-party vendor.

Foreign currency transaction (losses) gains, net. We had foreign currency transaction losses of $0.2 million and gains of less than $0.1 million for the three months ended March 31, 2020 and 2019, respectively. Foreign currency transaction gains and losses consisted of the realized and unrealized gains and losses from foreign currency-denominated cash balances, vendor payables and tax-related receivables from the Australian government, generally reflecting the fluctuation of the Australian dollar relative to the U.S. dollar.

Liquidity and Capital Resources

As of March 31, 2020, we had cash, cash equivalents and marketable debt securities totaling $63.9 million and outstanding principle balance on the Term Loan of $12.7 million. We invest our cash in money market funds, commercial paper, corporate bonds and U.S. government securities, with the primary objectives to preserve principal, provide liquidity and maximize income without significantly increasing risk.

Since our inception in November 2005, we have not generated any revenue and have incurred recurring net losses. As of March 31, 2020, we had an accumulated deficit of $399.9 million. Prior to our IPO in June 2014, we funded our operations primarily through sales of redeemable convertible preferred stock and, to a lesser extent, through the issuances of convertible promissory notes and a loan security agreement. From our inception through our IPO in June 2014, we received gross proceeds of $104.0 million from such transactions. In June 2014, we completed our IPO with net proceeds of $102.7 million after deducting underwriting discounts and commissions paid by us. We also incurred offering costs of $2.5 million related to the IPO. In January 2015, we completed a follow-on offering of our common stock, which resulted in the sale of 3,942,200 shares at a price of $35.00 per share. We received net proceeds from the follow-on offering of $130.0 million based upon the price of $35.00 per share and after deducting underwriting discounts and commissions paid by us. We also incurred offering costs of $0.5 million related to the follow-on offering. On July 2, 2018, we completed a public offering of our common stock, which resulted in the sale of 9,200,000 shares at a price of $7.50 per share, resulting in net proceeds of approximately $64.6 million after deducting underwriting discounts and commissions, as well as offering costs paid by us.

On November 9, 2018, we entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, with aggregate gross sales proceeds of up to $50.0 million, from time to time, through an at-the-market equity offering program under which Cowen will act as our sales agent. Through March 31, 2020 we have not sold any shares under the Sales Agreement.

On December 29, 2017, we entered into a loan and security agreement with Silicon Valley Bank, or the Term Loan. The Term Loan provided for borrowings of $20.0 million. On December 29, 2017, we received proceeds of $20.0 million from the issuance of a promissory note. The promissory note issued under the Term Loan is collateralized by substantially all of our personal property, other than our intellectual property. As of March 31, 2020 we had an outstanding principle balance on the Term Loan of $12.7 million.

Upon entering into this Term Loan, we are obligated to make monthly, interest-only payments until March 29, 2019 and, thereafter, to pay 33 consecutive, equal monthly installments of principal and interest from April 1, 2019 through December 1, 2021. The outstanding Term Loan bears a variable interest at an annual rate of 1.25% above the prime rate, which was 3.25% at March 31, 2020. In addition, a final payment equal to 8.0% of the Term Loan is due upon the earlier of the maturity date, acceleration of the Term Loan or prepayment of all or part of the Term Loan. We accrue the final payment amount of $1.6 million, to outstanding debt by charges to interest expense using the effective-interest method from the date of issuance through the maturity date.

Additionally, we, as the borrower, are required to maintain a minimum cash, cash equivalents and marketable debt securities balance at Silicon Valley Bank of no less than 105% of the total outstanding principal balance of the Term Loan, which as of March 31, 2020 was $13.4 million and as of December 31, 2019 was $15.3 million.

Further, as of 45 days after the Term Loan was entered in, we must maintain a balance of unrestricted cash, cash equivalents and marketable debt securities at Silicon Valley Bank in an amount not less than the greater of (i) $55.0 million and (ii) sixty-five percent (65%) of all of our cash, cash equivalents and marketable debt securities. If we do not meet this requirement it will not be considered an event of default provided we immediately secure 87.5% of the principal balance in a restricted cash account.

There are negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering or granting a security interest in our intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; permit the aggregate value of cash maintained by our Australian subsidiary not to exceed $4.0 million and certain other business transactions.

The Term Loan also includes events of default, the occurrence and continuation of any of which provides the lenders the right to exercise remedies against us and the collateral securing the loans under the Term Loan, including cash in the amount of the outstanding balance. These events of default include, among other things, failure to pay any amounts due under the Term Loan, insolvency, the occurrence of a material adverse event, the occurrence of any default under certain other indebtedness and a final judgment against us in an amount greater than $0.3 million. We have estimated that the risk of subjective acceleration under the material adverse events clause is reasonably possible, however not probable and therefore have classified the outstanding principal in current and long-term liabilities based on contractually scheduled principal payments. However, the assessment of such probability of the debt holder calling the debt is subjective and their actions and/or our related assessment could change in the future, which in turn would impact the classification of the debt balances.

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

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
	(in thousands)	
Cash used in operating activities	$ (4,616)	$ (12,471)
Cash provided by investing activities	18,193	807
Cash (used in) provided by financing activities	(1,808)	95
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 11,769	$ (11,569)

Net cash used in operating activities

During the three months ended March 31, 2020, operating activities used $4.6 million of cash, resulting from our net loss of $3.6 million and changes in our operating assets and liabilities of $1.8 million, partially offset by non-cash charges of $0.8 million. Our net loss was primarily attributed to our general and administrative expenses. Net cash used in changes in our operating assets and liabilities during the three months ended March 31, 2020, consisted primarily of a $0.3 million decrease in accounts payable and a $1.7 million decrease in accrued restructuring, partially offset by a $0.4 million decrease in prepaids and other current assets. Our net non-cash charges during the three months ended March 31, 2020, consisted primarily of stock-based compensation expense of $0.7 million.

During the three months ended March 31, 2019, operating activities used $12.5 million of cash, resulting from our net loss of $13.1 million and changes in our operating assets and liabilities of $1.2 million, partially offset by non-cash charges of $1.8 million. Our net loss was primarily attributed to research and development activities related to our MetAP2 program and our general and administrative expenses. Net cash used in changes in our operating assets and liabilities during the three months ended March 31, 2019, consisted primarily of a $0.4 million decrease in accounts payable and a $1.1 million decrease in accrued expenses and other, partially offset by a $0.5 decrease in prepaids and other current assets. Our net non-cash charges during the three months ended March 31, 2019, consisted primarily of stock-based compensation expense of $2.1 million.

Net cash provided by investing activities

During the three months ended March 31, 2020, investing activities provided $18.2 million of cash resulting from the proceeds from sales and maturities of marketable debt securities of $20.5 million, offset by the purchases of marketable debt securities of $2.3 million.

During the three months ended March 31, 2019, investing activities provided $0.8 million of cash resulting from the proceeds from sales and maturities of marketable debt securities of $34.3 million, offset by the purchases of marketable debt securities of $33.5 million.

Net cash (used in) provided by financing activities

During the three months ended March 31, 2020, financing activities used $1.8 million as a result of payments related to our notes payable.

During the three months ended March 31, 2019, net cash provided by financing activities of $0.1 million was the result of the exercise of common stock options and common stock purchased under our 2014 Employee Stock Purchase Plan.

Operating Capital Requirements and Liquidity

We have not generated product revenue or achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect that our existing cash, cash equivalents and marketable debt securities as of March 31, 2020, will enable us to fund our operating expenses and capital expenditure requirements for a period of at least one year from the issuance date of this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute their ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our future product development or future commercialization efforts or grant rights to develop and market our future product candidates, if any, that we would otherwise prefer to develop and market ourselves. Our future capital requirements will depend on many factors, including:

- our plans and expectations regarding the merger with Chondrial, including the expected completion of the merger;
- our strategies, goals, prospects, plans, expectations, forecasts or objectives with Chondrial or the combined company;
- our ability to resolve the deficiencies and regain compliance with the minimum bid price requirements of our common stock as set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on Nasdaq;
- the number and characteristics of any future product candidates we develop or may acquire;
- the scope, progress, results and costs of researching and developing any future product candidates, and conducting nonclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidate;
- the cost of manufacturing any future product candidates and any products that may achieve regulatory approval;
- the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation.

Since our inception in 2005, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2019, we had net operating loss carryforwards for federal and state income tax purposes of $55.7 million and $57.0 million, respectively, which begin to expire in 2026 and 2030, respectively. As of December 31, 2019, we had net operating loss carryforwards that were generated after December 31, 2017, of $21.2 million that do not expire. As of December 31, 2019, we also had available tax credit carryforwards for federal and state income tax purposes of $17.9 million and $4.2 million, respectively, which begin to expire in 2026 and 2022, respectively We have not completed a study to assess whether an ownership change, generally defined as a greater than 50% change (by value) in the equity ownership of our corporate entity over a three-year period, has occurred or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize our tax carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

Contractual Obligations and Commitments

During the three months ended March 31, 2020, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in our Annual Report.

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.

Application of Critical Accounting Policies

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United Sated, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that of our critical accounting policies which are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report, the following accounting policies involve the most judgment and complexity:

- valuation of stock-based awards.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no material changes to our critical accounting policies since December 31, 2019.

Recently Issued Accounting Pronouncements

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

Nasdaq Delisting Notice

On April 21, 2020, we received written notice, or the Notice, from the Listing Qualifications Department of Nasdaq notifying us that we are not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(1) for continued listing on Nasdaq. Nasdaq Listing Rule 5550(a)(1) requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of thirty (30) consecutive business days.

Nasdaq Listing Rule 5810(c)(3)(A) provides 180 calendar days to regain compliance. On April 16, 2020, Nasdaq announced it was providing temporary relief from continued listing bid price requirements through June 30, 2020. Under the relief the Company will have additional time to regain compliance with the listing bid price requirements with the compliance period beginning July 1, 2020. As such, the compliance period for us will expire on December 28, 2020. To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of ten (10) consecutive business days.

If we do not regain compliance by December 28, 2020, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the staff of Nasdaq, or the Staff, that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that our securities would be subject to delisting. In the event of such a notification, we may appeal the Staff's determination to delist our securities, but there can be no assurance the Staff would grant our request for continued listing.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the Nasdaq Listing Rules.

If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects. We will consider available options to resolve the deficiencies and regain compliance with all applicable Nasdaq Listing Rules.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Fluctuation Risk

Our cash, cash equivalents, and marketable debt securities as of March 31, 2020 consisted of cash, corporate bonds, commercial paper, U.S. government securities and money market accounts. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. If market interest rates were to increase immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels as of March 31, 2020, the net fair value of our interest-sensitive financial instruments would have resulted in a hypothetical decline of less than $0.1 million.

Foreign Currency Exchange Risk

Foreign currency transaction exposure results primarily from transactions with our contract research organizations, or CROs, other providers related to our clinical trials and our Australia research and development tax incentive receivable that are denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded by us, primarily the Australian dollar. Any transaction gains or losses resulting from currency fluctuations is recorded on a separate line in our condensed consolidated statement of operations. Net foreign currency transaction losses of $0.2 million and gains of less than $0.1 million were recorded for the three months ended March 31, 2020 and 2019, respectively.

Currently, our largest foreign currency exposures are those with respect to the Australian dollar. Relative to foreign currency exposures existing as of March 31, 2020, a 10% unfavorable movement in foreign currency exchange rates would expose us to an increased net loss. For the three months ended March 31, 2020, we estimated that a 10% unfavorable movement in foreign currency exchange rates would have increased our net loss by $0.2 million. This amount is based on a sensitivity analysis performed on our financial position as of March 31, 2020. We have experienced and will continue to experience fluctuations in our net loss as a result of revaluing our assets and liabilities that are not denominated in the functional currency of the entity that recorded the asset or liability. At this time, we do not hedge our foreign currency risk.

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.

Based on this evaluation, 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 based upon the evaluation described above that, as of March 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business in accordance with the Exchange Act.

Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 2020, there have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(d) under the Exchange Act) 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

We are not currently party to any material litigation or other material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, or Quarterly Report, and in our other public filings before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report and in our other public filings. The trading price of our common stock could decline due to any of these risks, and as a result, you may lose all or part of your investment. For additional risks related to Chondrial's business and the risks related to the combined company if the merger is completed, see the Proxy Statement filed with the SEC on April 29, 2020.

Risks Related to the Merger

If the proposed merger with Chondrial is not consummated, our business could suffer materially and our stock price could decline.

The consummation of the proposed merger with Chondrial is subject to a number of closing conditions, including the approval by our stockholders, approval by NASDAQ of our application for initial listing of our common stock in connection with the merger, and other customary closing conditions. We are targeting a closing of the transaction in the second quarter of 2020.

If the proposed merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows:

- We have incurred and expect to continue to incur significant expenses related to the proposed merger with Chondrial even if the merger is not consummated.
- The merger agreement contains covenants relating to our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the merger agreement and the closing of the merger. As a result, significant business decisions and transactions before the closing of the merger require the consent of Chondrial. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company. If the merger agreement is terminated after we have invested significant time and resources in the transaction process, we will have a limited ability to continue our current operations without obtaining additional financing to fund our operations.
- We could be obligated to pay Chondrial a $3,375,000 termination fee in connection with the termination of the merger agreement, depending on the reason for the termination.
- We could be obligated to pay Chondrial a $350,000 expense reimbursement in connection with the termination of the merger agreement, depending on the reason for the termination.
- Our collaborators and other business partners and investors in general may view the failure to consummate the merger as a poor reflection on our business or prospects.
- Some of our suppliers, collaborators and other business partners may seek to change or terminate their relationships with us as a result of the proposed merger.
- As a result of the proposed merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities. Additionally, pursuant to the merger agreement, all of our employees will be terminated effective as of the closing.
- Our management team may be distracted from day to day operations as a result of the proposed merger.
- The market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed merger will be completed.

In addition, if the merger agreement is terminated and our board of directors, or our Board, determines to seek another business combination, we may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the merger. In such circumstances, our Board may elect to, among other things, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we receive may be less attractive than the consideration to be received by us pursuant to the merger agreement.

If we do not successfully consummate the merger or another strategic transaction, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the merger will be completed. If the merger is not completed, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

The amount of merger consideration may vary depending on the amount of our net cash as of a certain determination date prior to closing and the date on which the closing occurs, which could result in our stockholders owning a smaller percentage of the combined company than expected.

Under the terms of the merger agreement, the number of shares of our common stock to be issued to Chondrial's stockholder at the closing of the merger will be determined based on an exchange ratio, which will be calculated based on the total number of outstanding shares of our common stock and Chondrial common stock, each on a fully-diluted basis, and the respective valuations of Chondrial and us, as of immediately prior to the closing of the merger. If the closing had occurred on or before March 31, 2020 and there was no adjustment to the closing valuation of us (as described below), then immediately following the effective time of the merger, Chondrial’s stockholder would own, or hold rights to acquire, 60% of the common stock of the combined company, on a fully-diluted basis, and our existing stockholders would own or hold rights to acquire 40% of the common stock of the combined company, on a fully-diluted basis. The respective valuations of Chondrial and us, and the corresponding ownership percentages of Chondrial’s stockholder and our existing stockholders, will likely adjusted upward or downward based on the date the closing occurs and the net cash balance (defined in the merger agreement as cash, cash equivalents and marketable debt securities minus certain outstanding liabilities) of us as of a determination date prior to the closing of the merger, and as a result, either our stockholders could own less of the combined company than expected. As the closing of the merger will occur after March 31, 2020, our target net cash and lower target net cash and upper target net cash amounts will be reduced by $21,311 per day beginning on March 31, 2020 through the closing date of the merger, and the Chondrial valuation will be increased by $111,656 per day beginning on March 31, 2020 through the closing date of the merger, resulting in a corresponding adjustment to the exchange ratio and an increase to the ownership percentage of Chondrial’s stockholder in the combined company. There can be no assurances as to our level of net cash between now and closing or as to the date the closing will occur.

Our net cash may be less than $30,000,000 at the closing of the merger, which would cause a condition to Chondrial’s obligation to consummate the merger to fail to be satisfied and may result in the termination of the merger agreement.

We are required to have a net cash balance of at least $30,000,000 at the closing of the merger as a condition to Chondrial’s obligation to consummate the merger. For purposes of the merger agreement, net cash is subject to certain reductions, including, without limitation, accounts payable, accrued expenses (except those related to the merger), current liabilities payable in cash, unpaid expenses related to the merger and certain other unpaid obligations, including outstanding lease obligations. The liability with regards to our outstanding lease obligations is a large component of our net cash and COVID-19 has created uncertainties surrounding our ability to take the steps necessary to sublease or negotiate a buy-out of our existing leases. In the event that our net cash falls below this threshold, a condition to Chondrial’s obligation to consummate the merger will fail to be satisfied and Chondrial will have the right to terminate the merger agreement at an outside date of September 17, 2020 (subject to extension as provided in the merger agreement) if our net cash continues to be lower than the $30,000,000 threshold.

Some of our officers and directors have conflicts of interest that may influence them to support or approve the merger.

Our officers and directors participate in arrangements that provide them with interests in the merger that are different from yours, including, among others, their continued service as a director of the combined company, retention and severance benefits, the acceleration of restricted stock and option vesting and continued indemnification. These interests, among others, may influence our officers and directors to support or approve the merger.

The merger may be completed even though material adverse changes may result from the announcement of the merger, industry-wide changes and other causes.

In general, either party can refuse to complete the merger if there is a material adverse change affecting the other party between December 17, 2019, the date of the merger agreement, and the closing. However, some types of changes do not permit either party to refuse to complete the merger, even if such changes would have a material adverse effect on us or Chondrial, to the extent they resulted from the following and do not have a materially disproportionate effect on us or Chondrial, as the case may be:

- the announcement or pendency of the merger agreement or the transactions contemplated thereby;
- the taking of any action, or the failure to take any action, by any party that is required to comply with the terms of the merger agreement;
- any natural disaster or any act or threat of terrorism or war anywhere in the world, any armed hostilities or terrorist activities anywhere in the world, any threat or escalation or armed hostilities or terrorist activities anywhere in the world or any governmental or other response or reaction to any of the foregoing;
- any change in generally accepted accounting principles or any change in applicable laws, rules or regulations or the interpretation thereof;
- general economic or political conditions or conditions generally affecting the industries in which either party and its subsidiaries operate;
- with respect to us, any change in the stock price or trading volume of our common stock;
- with respect to us, subject to certain exceptions, a change in the listing status of our common stock on NASDAQ; or
- with respect to Chondrial, any change in the cash position of Chondrial or its subsidiaries which results from operations in the ordinary course of business.

If adverse changes occur but we and Chondrial must still complete the merger, the combined company's stock price may suffer.

The market price of the combined company's common stock may decline as a result of the merger.

The market price of the combined company's common stock may decline as a result of the merger for a number of reasons including if:

- the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts;
- the effect of the merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect on the combined company's business and prospects from the merger.

Our stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the merger, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price following the merger.

During the pendency of the merger, we may not be able to enter into a business combination with another party and will be subject to contractual limitations on certain actions because of restrictions in the merger agreement.

Covenants in the merger agreement impede the ability of us or Chondrial to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the merger. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors. In addition, while the merger agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of our common stock, a tender offer for our common stock, a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to such party's stockholders.

Because the lack of a public market for Chondrial common stock makes it difficult to evaluate the fairness of the merger, Chondrial's stockholder may receive consideration in the merger that is greater than or less than the fair market value of Chondrial common stock.

The outstanding share capital of Chondrial is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Chondrial. Since the percentage of our equity to be issued to Chondrial's stockholder was determined based on negotiations between the parties, it is possible that the value of our common stock to be issued in connection with the merger will be greater than the fair market value of Chondrial. Alternatively, it is possible that the value of the shares of our common stock to be issued in connection with the merger will be less than the fair market value of Chondrial.

The combined company will incur significant transaction costs as a result of the merger, including investment banking, legal and accounting fees. In addition, the combined company will incur significant consolidation and integration expenses which cannot be accurately estimated at this time. These costs could include the possible relocation of certain operations from Massachusetts to other offices of the combined company as well as costs associated with terminating existing office leases and the loss of benefits of certain favorable office leases. Actual transaction costs may substantially exceed Chondrial's estimates and may have an adverse effect on the combined company's financial condition and operating results.

Failure of the merger to qualify as a reorganization within the meaning of Section 368(a) of the Code could harm the combined company.

The parties intend for the merger to qualify as a reorganization within the meaning of Section 368(a) of the Code, as amended. To comply with the requirements for a Section 368(a) reorganization, certain structural and other requirements for the transaction must be met; if not satisfied, Chondrial's stockholder could be subject to tax liability.

The merger is expected to result in a limitation on our ability to utilize our net operating loss carryforward.

Under Section 382 of the Code, use of our net operating loss carryforwards, or NOL, will be limited if we experience an "ownership change." For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We are expected to experience an ownership change as a result of the merger and therefore our ability to utilize our NOLs and certain credit carryforwards remaining at the effective time will be limited. The limitation will be determined by the fair market value of our common stock outstanding prior to the ownership change, multiplied by the applicable federal rate. Limitations imposed on our ability to utilize NOLs could cause U.S. federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs.

Certain stockholders could attempt to influence changes which could adversely affect our operations, financial condition and the value of our common stock.

Our stockholders may from time-to-time seek to acquire a controlling stake, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, and could disrupt our operations and divert the attention of our Board and senior management from the pursuit of the proposed merger transaction. These actions could adversely affect our operations, financial condition, our ability to consummate the merger and the value of our common stock.

Chondrial and us may become involved in securities litigation or stockholder derivative litigation in connection with the merger, and this could divert the attention of our management and Chondrial management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. Chondrial and us may become involved in this type of litigation in connection with the merger, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business, Chondrial and the combined company.

Failure to complete the merger may result in us and Chondrial paying a termination fee or expenses to the other party and could harm the price of our common stock and the future business and operations of each company.

If the merger is not completed and the merger agreement is terminated under certain circumstances, we or Chondrial may be required to pay the other party a termination fee of $3,375,000 and/or an expense reimbursement of up to $350,000. Even if a termination fee or expense reimbursement is not payable in connection with a termination of the merger agreement, we and Chondrial will have incurred significant fees and expenses, which must be paid whether or not the merger is completed. Further, if the merger is not completed, it could significantly harm the market price of our common stock.

The exchange ratio is not adjustable based on the market price of our common stock so the merger consideration at the closing may have greater or lesser value than the market price at the time the merger agreement was signed.

The merger agreement has set the exchange ratio for Chondrial common stock, and the exchange ratio is based on the outstanding Chondrial common stock and our outstanding common stock, in each case immediately prior to the closing of the merger. Applying the exchange ratio formula in the merger agreement, the former Chondrial stockholders immediately before the merger are expected to own 60% of our outstanding capital stock immediately following the merger, and our stockholders immediately before the merger are expected to own approximately 40% of our outstanding capital stock immediately following the merger, subject to certain assumptions. Under certain circumstances further described in the merger agreement, however, these ownership percentages may be adjusted upward or downward based on the date the closing occurs and the cash levels of the respective companies at the closing of the merger, and as a result, our stockholders could own less of the combined company than expected.

Any changes in the market price of our common stock before the completion of the merger will not affect the number of shares of our common stock issuable to Chondrial's stockholders pursuant to the merger agreement. Therefore, if before the completion of the merger the market price of our common stock declines from the market price on the date of the merger agreement, then Chondrial's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the merger agreement. Similarly, if before the completion of the merger the market price of our common stock increases from the market price of our common stock on the date of the merger agreement, then Chondrial's stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the merger agreement. The merger agreement does not include a price-based termination right. Because the exchange ratio does not adjust as a result of changes in the market price of our common stock, for each one percentage point change in the market price of our common stock, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration payable to Chondrial's stockholders pursuant to the merger agreement.

Certain provisions of the merger agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the merger agreement.

The terms of the merger agreement prohibit each of us and Chondrial from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our Board determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and that failure to cooperate with the proponent of the proposal would be reasonably likely to be inconsistent with our Board fiduciary duties.

If the conditions to the merger are not met, the merger may not occur.

Even if share issuance and reverse stock split are approved by our stockholders and Chondrial's, specified conditions must be satisfied or waived to complete the merger. These conditions are set forth in the merger agreement. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the merger will not occur or will be delayed, and we and Chondrial each may lose some or all of the intended benefits of the merger.

General Company-Related Risks

Our ability to consummate the proposed merger with Chondrial, depends on our ability to retain our employees required to consummate a strategic transaction as previously announced.

Our ability to consummate the proposed merger with Chondrial depends upon our ability to retain our employees required to consummate a strategic transaction, the loss of whose services may adversely impact the ability to consummate the merger. On September 10, 2019, we announced a reduction in workforce that includes reducing employees by approximately 48%, and when combined with the reduction in workforce announced on July 24, 2019 and other attrition in 2019, resulted in a total reduction of employees of approximately 70%.

On September 10, 2019, we also announced a retention plan for the remaining executive officers and implemented retention plans for the other remaining employees that is designed to retain the employees required to explore and consummate a strategic transaction. We have entered into amendments to severance and change in control agreements with certain of our executive officers, but they may terminate their employment with us at any time.

With any change in leadership, there is also a risk to retention of employees, as well as the potential for disruption to our exploration and consummation of a strategic alternative as well as business operations, initiatives, plans and strategies.

In addition, responses to the COVID-19 pandemic have resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, stay-at-home orders, and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely, or in the event that our employees are personally affected by COVID-19, it may adversely impact our ability to consummate the merger, disrupt our operations or increase the risk of a cybersecurity incident.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business and stock price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we assess the effectiveness of our disclosure controls and procedures quarterly and the effectiveness of our internal control over financial reporting at the end of each fiscal year.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are applicable to us as a public company. If we fail to staff our accounting, finance and information technology functions adequately or maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and our stock price may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our common stock.

The ongoing COVID-19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition.

Our business could be materially adversely affected, directly or indirectly, by the ongoing COVID-19 pandemic. National, state and local governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, business closures, cancellations of public gatherings and other measures. Organizations and individuals are taking additional steps to avoid or reduce infection, including limiting travel and staying home from work. These measures are disrupting normal business and governmental operations both in and outside of affected areas and have had significant negative impacts on businesses and financial markets worldwide.

We continue to monitor our operations and applicable government recommendations, and we have made modifications to our normal operations because of the COVID-19 pandemic, including requiring employees to work remotely. Notwithstanding these measures, the COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on taking similar measures. We may experience limitations in employee resources, including because of sickness of employees or their families or the desire of employees to avoid contact with individuals or large groups of people. In addition, we have experienced and will continue to experience disruptions to our business operations resulting from quarantines, self-isolations and other restrictions on the ability of our employees to perform their jobs. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able to execute on our business strategy, our operations may be negatively impacted, and the closing of our merger with Chondrial Therapeutics, Inc. may be affected.

We have already experienced business disruptions from the COVID-19 pandemic, for example, the COVID-19 pandemic has created uncertainties surrounding our ability to take the steps necessary to sublease or negotiate a buy-out of our existing leases. While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business, operations, and employees, the continued spread of COVID-19 including the measures taken by governments, actions taken to protect employees and the broad impact of the pandemic on all business activities may continue to materially and adversely affect our business, results of operations and financial condition.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including disruptions as a result of the COVID-19 pandemic. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our future product candidates, if any and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our internal computer systems, or those of our third-party contract research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our future product candidates.

Despite the implementation of security measures, our internal computer systems and those of our third-party contract research organizations, or CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The number and complexity of these threats continue to increase over time, including as a result of employees working remotely in response to COVID-19. While we have not experienced any such system failure or accident, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of nonclinical or clinical trial data for our future product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our future product candidates could be delayed.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate such businesses with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such transaction including the proposed merger with Chondrial, we will achieve the expected synergies to justify the transaction.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of any future product candidates in clinical trials, if any, and the sale of any future product candidates, if developed and approved, exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise who have come into contact with our future product candidates. For example, we may be sued if any product we develop allegedly causes injury or death or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- withdrawal of patients from our clinical trials;
- substantial monetary awards to patients or other claimants;
- decreased demand for our future product candidates following marketing approval, if obtained;
- damage to our reputation and exposure to adverse publicity;
- increased U.S. Food and Drug Administration, or FDA, warnings on product labels;

- litigation costs;
- distraction of management's attention from our primary business;
- loss of revenue; and
- the inability to successfully commercialize our future product candidates, if approved.

For our prior clinical trials, we have maintained product liability insurance coverage with a $10.0 million annual aggregate coverage limit. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. If and when we obtain marketing approval for our future product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may not be able to obtain this product liability insurance on commercially reasonable terms. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or the TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate, limitation of the tax deduction for interest expense, limitation of the deduction for net operating losses and elimination of net operating loss carrybacks and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). In 2017, our net deferred tax assets and liabilities were revalued at the newly enacted U.S. corporate rate.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

Since our inception in 2005, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2019, we had net operating loss carryforwards for federal and state income tax purposes of $55.7 million and $57.0 million, respectively, which begin to expire in 2026 and 2030, respectively. As of December 31, 2019, we also had available tax credit carryforwards for federal and state income tax purposes of $17.9 million and $4.2 million, respectively, which begin to expire in 2026 and 2022, respectively. Under Section 382 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Our follow-on public offering, initial public offering, or IPO, private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of our follow-on public offering, IPO, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study. The reduction of the corporate tax rate under TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, net operating losses generated after December 31, 2017 will not be subject to expiration. As of December 31, 2019, we had net operating loss carryforwards that were generated after December 31, 2017, of $21.2 million that do not expire.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted an insider trading policy and a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may not be successful in our efforts to identify or discover additional product candidates.

Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans or expand our internal efforts and growth.

Our future drug development programs and the potential commercialization of our future product candidates, if any, will require substantial additional cash to fund expenses. For our future product candidates, if any, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates in some or all markets.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration for any future product candidates will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the applicable product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our future product candidates, if any. The terms of any collaboration or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing license agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable or unwilling to do so, we may have to curtail the development of our future product candidates for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay potential commercialization in some or all markets or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense, including potentially increasing our infrastructure and investment outside the United States. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our future product candidates, if any, or bring them to market and generate product revenue. In addition, such efforts may require diversion of a disproportionate amount of our attention away from other day-to-day activities and require devotion of a substantial amount of our time to managing these expansion activities.

In addition, any future collaborations that we enter into for our future product candidates may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Our Common Stock

We may not be able to comply with all applicable listing requirements or standards of the NASDAQ Global Market and Nasdaq could delist our common stock.

Our common stock is currently listed on the NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards. One such requirement is that we maintain a minimum bid price of at least $1.00 per share for our common stock. For example, in April 2020, we received a letter from the Listing Qualifications Department of the Nasdaq advising us that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Price Requirement.

Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice the closing bid price of our common stock is at or above $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on Nasdaq, absent noncompliance with any other requirement for continued listing. On April 16, 2020, Nasdaq announced it was providing temporary relief from continued listing bid price requirements through June 30, 2020. Under the relief we will have additional time to regain compliance with the listing bid price requirements with the compliance period beginning July 1, 2020. As such, the compliance period for us will expire on December 28, 2020.

If we do not regain compliance with the Minimum Bid Price Requirement within an allotted grace period, then under Nasdaq Listing Rule 5810(c)(3)(A)(i) we may transfer to The Nasdaq Capital Market, provided that we meet the applicable market value of the publicly held shares requirement for continued listing as well as all other standards for initial listing of our common stock on The Nasdaq Capital Market and we notify Nasdaq of our intention to cure the deficiency during a second grace period. Following a transfer to The Nasdaq Capital Market, we may be afforded an additional 180-days to regain compliance with the Minimum Bid Price Requirement. If we do not regain compliance with the Minimum Bid Price Requirement within the allotted grace period, our shares of common stock would be subject to delisting. In the event that our common stock is not eligible for continued listing on Nasdaq or another national securities exchange, trading of our common stock could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by security analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if our stock is not listed on a major exchange.

In September 2019, we received a similar Notice that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(1) for continued listing on Nasdaq. Prior to the expiration of the then compliance period, we came into compliance with the minimum bid price requirements and we were notified by Nasdaq of such compliance and the matter was closed.

We expect that our stock price will continue to fluctuate significantly.

The market price of shares of our common stock, similar to the market price of shares of common stock of other biopharmaceutical companies, is subject to wide fluctuations. From January 1, 2020 to March 31, 2020 the daily closing price of our common stock on the NASDAQ Global Market ranged from a high of $1.49 to a low of $0.66 and will continue to be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the COVID-19 pandemic and its global economic impact;
- plans and expectations regarding the merger with Chondrial, including the expected completion of the merger;
- plans for, progress of, or results from nonclinical studies and clinical trials of our future product candidates;
- the failure of the FDA to permit an investigational new drug application, or IND, to go into effect for our future product candidates, if any;
- the failure of the FDA or the European Medicines Agency, or EMA, to approve our future product candidates, if any;
- our ability to establish an adequate safety margin and profile for our future product candidates, if any;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- regulatory or legal developments in the United States and other countries;
- failure of our future product candidates, if successfully developed and approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- our ability to raise additional capital and the terms on which we can raise it;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- additions or departures of key personnel;
- discussion of us or our stock price by the press and by online investor communities; and
- other risks and uncertainties described in these risk factors.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and NASDAQ listed and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock.

Our executive officers, directors, and principal stockholders exercise significant control over our company.

As of April 30, 2020, the existing holdings of our executive officers, directors, principal stockholders and their affiliates, including investment funds affiliated with Atlas Ventures, 683 Capital Management, LLC, AIGH Capital Management, LLC, Renaissance Technologies LLC, Sphera Funds Management Ltd., and Sio Capital Management, LLC, represent beneficial ownership, in the aggregate, of approximately 48.5% of our common stock. As a result, these stockholders, if they act together, are able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. The concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing our change of control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control.

Future sales of our common stock may cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies, including us, have experienced significant stock price volatility in the past.

We are a "smaller reporting company" and have availed ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are a smaller reporting company, and we will remain a smaller reporting company as long as our voting and non-voting common shares held by non-affiliates is less than $75 million measured on the last business day of our second fiscal quarter; or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We may choose to take advantage of some, but not all, of the available exemptions for smaller reporting companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our shares price may be more volatile.

We have never paid dividends on our common stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid dividends on any of our common stock to date and we currently intend to retain all of our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gains for our common stockholders for the foreseeable future. Consequently, in the foreseeable future, our common stockholders will likely only experience a gain from their investment in our common stock if the price of our common stock increases.

If equity research analysts do not continue to publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Anti-takeover provisions contained in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions:

- creating a classified board of directors whose members serve staggered three-year terms;
- authorizing "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors and officers;
- limiting the ability of our stockholders to call and bring business before special meetings;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and
- providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Risks Related to Product Development, Regulatory Approval and Commercialization

We cannot be certain that we will be able to successfully complete clinical trials for our future product candidates, if any, obtain regulatory approval for any product candidates or successfully commercialize any product candidates, if approved.

Before our future product candidates, if any, can be marketed, our IND application or other comparable regulatory approvals must go into effect permitting the conduct of clinical trials, and we must then successfully complete human testing. The FDA and other comparable foreign regulatory agencies must approve our New Drug Application, or NDA, or comparable regulatory submissions. Even after successful completion of clinical testing, there is a risk that the FDA or other regulatory agencies may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our submission. Even if the FDA approves our NDA, we may be unable to successfully commercialize our product candidates.

It is possible that the FDA or other regulatory agencies will not approve any application that we may submit. It is possible that our future product candidates, if any, may not obtain appropriate regulatory approvals necessary for us to commence clinical trials for our future product candidates, if any. Any delay or failure in obtaining required approvals could have a material adverse effect on our business. This process can take many years and will likely require the expenditure of substantial resources beyond the proceeds we currently have on hand.

Favorable results from nonclinical studies and clinical trials to date are not necessarily predictive of the results of additional nonclinical studies or later-stage clinical trials of our future product candidates, if any.

Favorable results from our nonclinical studies may not necessarily be predictive of the results from clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in nonclinical and early-stage clinical development. In particular, we have suffered significant setbacks in later-stage clinical trials of our former lead product candidates, beloranib and ZGN-1061, after achieving positive results in nonclinical and clinical development, and we cannot be certain that we will not face similar setbacks in our development of our future product candidates, if any. The setbacks in later-stage clinical development have been caused by, among other things, nonclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported or understood adverse events. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA and/or EMA approval. If we fail to produce positive results in our later-stage clinical trials of any future product candidates, if any, the development timeline and regulatory approval and commercialization prospects for any future product candidates, if any, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Our future product candidates, if any, may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our future product candidates, if any, could cause us or regulatory authorities such as the FDA to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Further, if any future product candidates receive marketing approval and we or others identify undesirable side effects caused by the product (or any other similar product) after the approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may request that we withdraw the product from the market or may limit their approval of the product through labeling or other means;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication or a precaution;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may decide to remove the product from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Failures or delays in the commencement or completion of our clinical trials of our future product candidates could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

Despite the guidance we may receive from the FDA, the EMA, or other applicable regulatory authorities, any of these regulatory authorities can change their positions on the acceptability of our clinical trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we expect. Successful completion of such clinical trials is a prerequisite to submitting an NDA to the FDA and a Marketing Authorization Application to the EMA or other regulatory authorities and, consequently, the ultimate approval and commercial marketing of our future product candidates, if any. We do not know whether any clinical trials for our future product candidates will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA, or other applicable regulatory authorities, may deny permission to begin or continue clinical trials, including for certain indications, we want to conduct;

- delays in regulatory filings or receiving regulatory authorizations of IND applications, or clinical trial authorization applications that may be required;
- unfavorable results from our nonclinical studies, thus the FDA, or other applicable regulatory authorities, may require additional nonclinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining Institutional Review Board, or IRB, and/or ethics committee approval to conduct a clinical trial at a prospective site or sites in the United States, or other country;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- difficulties in retaining or recruiting clinical investigators and/or patients in our future clinical trials;
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trial, lack of efficacy, side effects, screening and monitoring measures, personal issues or loss of interest;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- the FDA or the applicable regulatory authorities, may disagree with our clinical trial designs, our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials; and
- reports from nonclinical or clinical testing of other therapies that raise safety or efficacy concerns.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, other regulatory authorities, the IRBs or ethics committees, at the sites where the IRBs or ethics committees are overseeing a clinical trial, a data monitoring committee overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- as a result of disruptions related to COVID-19;
- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other applicable regulatory authorities, that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a partial clinical hold or a full clinical hold;
- unforeseen safety issues, including any that could be identified in our nonclinical studies or in the clinical studies of drugs in the same class as our future product candidates, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements, FDA guidance or guidance from other regulatory agencies or unanticipated events during our clinical trials of our future product candidates, may occur, which may result in changes to clinical trial protocols or additional clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA guidance or guidance from EMA or unanticipated events during our future clinical trials, if any, may force us to adjust our clinical program. The FDA, the EMA, or the applicable regulatory authorities may impose additional clinical trial and/or nonclinical study requirements. Amendments to our future clinical trial protocols would require resubmission to the FDA or other applicable regulatory authorities as well as IRBs and ethics committees for review and approval, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional clinical trials and/or nonclinical studies, the commercial prospects for our future product candidates may be harmed and our ability to generate product revenue will be delayed.

We have relied on, and expect that we will continue to rely, on third parties to conduct any future clinical trials for our future product candidates, if any. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to develop and obtain regulatory approval for or commercialize any future product candidates, and our business could be substantially harmed.

We entered into agreements with third-party CROs to provide monitors for and to manage data for our prior clinical trials. We relied heavily on these parties for execution of past clinical trials and may continue to rely on these parties for clinical trials for our future product candidates, if any, but we only control certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through the clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have disruptions, delays or difficulties as a result of and related to COVID-19;
- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials in the future, if any, and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs must comply with requirements for Good Clinical Practice, or GCPs, which are legal requirements enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites, IRBs, and other vendors that may be involved in the clinical development of new products. If we or our investigators or CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials, if any, may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials comply with GCPs. In addition, our future clinical trials, if any, must be conducted with products produced under current Good Manufacturing Practices, or cGMPs, regulations to assure the identity, strength, quality, and purity of our drug product candidates being used in the clinical trials, as well as the to-be-marketed formulation and product. Our failure or the failure of our CROs and/or contract manufacturing organizations, or CMOs, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action, up to and including, civil and criminal penalties.

Although we design our clinical trials, in the past, investigators and CROs have conducted all of our clinical trials. As a result, many important aspects of our drug development programs have been outside of our direct control. In addition, the investigators or CROs may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA or comparable foreign laws and regulations during the conduct of our clinical trials. If the investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us, or fail to comply with regulatory requirements, the development and commercialization of our future product candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these investigators or CROs will devote to our future product candidates. If we are unable to rely on clinical data collected by our investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party investigators or CROs terminate, we may not be able to enter into arrangements with alternative investigators or CROs in a timely manner, or at all. If investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our future product candidates. As a result, our financial results and the commercial prospects for our future product candidates in the subject indications would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We have no experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. As a result, we are dependent on third-party manufacturers, as well as on third parties for our supply chain, and if we experience problems with any third parties, or the actual demand for our future product candidates, if any, exceed our forecasts, the manufacture of adequate supplies of our future product candidates or products could be delayed.

We do not own or operate facilities for the manufacture of our future product candidates, if any. We currently have no plans to build our own manufacturing facilities for clinical or commercial operations. We have in the past relied on contract manufacturing organizations, or CMOs, for the chemical manufacture of active pharmaceutical ingredient and for the production of final product formulation and packaging for clinical trials, and expect to rely on CMOs for any future product candidate we are able to advance into clinical development. Although alternative third party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers should we commence clinical development of any future product candidate. We may encounter technical difficulties or delays in the transfer of manufacturing on a commercial scale to third party manufacturers. We may be unable to enter into agreements for commercial supply with third party manufacturers, or may be unable to do so on acceptable terms. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of any future product candidates, or market or distribute them.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates and could cause us to incur higher costs and prevent us from commercializing our product candidates successfully. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of products, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties. We are also unable to predict how changing global economic conditions or potential global health concerns such as COVID-19 will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for a clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our future product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. If our CMOs cannot manufacture sufficient quantity to meet the demand for our product candidates after regulatory approval, there would be a shortage in supply which would negatively impact our revenue from the sale of our product candidates. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA.

Even if we receive marketing approval for a product candidate in the United States, we may never receive regulatory approval to market such product candidate outside of the United States.

We may pursue marketing approval for certain of our future product candidates in the United States, the EU and in other countries worldwide. In order to market any product outside of the United States, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries, including potential additional clinical trials and/or nonclinical studies. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. In addition, on January 31, 2020, the United Kingdom government completed the process to leave the EU, or Brexit. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to EU markets either during a transitional period or more permanently. Brexit could lead to legal uncertainty and potentially divergent national laws and regulation as the United Kingdom determines which EU laws to replace or replicate. Marketing approval in one country does not necessarily ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process or commercial activities in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market a product candidate in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

Even if we receive marketing approval for a product candidate, it may not achieve broad market acceptance, which would limit the revenue that we generate from its sales.

The commercial success of a product candidate, if developed and approved for marketing by the FDA or EMA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our future product candidates, if any, among the medical community, including physicians, patients, advocacy groups and healthcare payors. Market acceptance of a product candidate, if approved, will depend on a number of factors, including, among others:

- the relative convenience and ease of administration of our future product candidates;
- the prevalence and severity of any adverse side effects associated with a product candidate;
- limitations or warnings contained in the labeling approved for a product candidate by the FDA, EMA, or other regulatory authorities, such as a “black box” warning;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of a product candidate through marketing efforts;
- our ability to obtain sufficient third party coverage or reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of third party coverage; and
- the likelihood that the FDA may require development of a Risk Evaluation and Mitigation Strategies, or REMS, as a condition of approval or post-approval or may not agree with our proposed REMS or may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

If a product candidate is approved but does not achieve an adequate level of acceptance by patients, advocacy groups, physicians and payors, we may not generate sufficient revenue from a product candidate to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that a product candidate also provides incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of a product candidate may require significant resources and may never be successful.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell a product candidate, we may not be able to generate any revenue.

We do not currently have an established infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market any future product candidate, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected.

Even if we receive marketing approval for any future product candidate, we may still face future development and regulatory difficulties.

Even if we receive marketing approval for a future product candidate, if any, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of our product candidates, or may impose ongoing requirements for potentially costly post-approval studies. A product candidate will also be subject to ongoing FDA and EMA requirements governing the labeling, packaging, storage and promotion of the product and recordkeeping and submission of safety and other post-market information. The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. Any REMS required by the FDA may lead to increased costs to assure compliance with post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue. Additionally, the FDA may require post-marketing studies and/or post-marketing requirements that could represent and result in additional restrictions and/or limitations for the product.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and other regulations. If we or a regulatory agency discover problems with any future product candidate, such as adverse events of unanticipated severity or frequency, or problems with the facility where any future product candidate is manufactured, a regulatory agency may impose restrictions on a product candidate, the manufacturer or us, including requiring withdrawal of any future product candidate from the market or suspension of manufacturing. If we or the manufacturing facilities for a product candidate fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

The FDA’s policies may change and additional government regulations may be enacted. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize a product candidate in foreign markets for which we may rely on collaborations with third parties. If we commercialize a product candidate in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for a product candidate in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of a product candidate could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We are subject to healthcare laws and regulations, and health information privacy and security laws, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any future product candidates, if approved. Our future arrangements with third party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our future product candidates, if any, and if we obtain marketing approval. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal false claims laws impose criminal and civil penalties, including those from civil whistleblower or qui tam actions pursuant to the federal False Claims Act, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements, sometimes referred to as the "Sunshine Act," under the Patient Protection and Affordable Care Act, require manufacturers of drugs, devices, biologics, and medical supplies to report to the Department

of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

In addition, regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the EU adopted a new regulation governing data practices and privacy called the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on service providers. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we operate.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we receive marketing approval for our future product candidates physicians may prescribe our product candidates, if any, to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion and required that they enter into corporate integrity agreements with the Office of Inspector General of the Department of Health and Human Services. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if approved, reimbursement policies could limit our ability to sell product candidates, if any, that we elect to sell on our own.

If approved by regulatory authorities, market acceptance and sales of product candidates, if any, that we elect to sell on our own will depend on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for those medications. Cost containment is a primary concern in the U.S. healthcare industry and elsewhere.

Government authorities and these third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for product candidates that we elect to sell on our own and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, product candidates, if any, that we elect to sell on our own. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize product candidates that we elect to sell on our own.

In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of product candidates that we elect to sell on our own with other available therapies. If reimbursement for product candidates that we elect to sell on our own is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our future drug candidates, if any, and affect the prices we may obtain.

The Affordable Care Act, or the ACA, has a significant impact on the healthcare industry. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The current presidential administration has indicated that enacting changes to the ACA is a legislative priority and has alternatively discussed repealing and replacing the ACA. While Congress has not passed repeal legislation to date, the 2017 Tax Reform Act includes a provision repealing the individual mandate, effective January 1, 2019. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. In addition, the Centers for Medicare and Medicaid Services, or CMS, has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through these marketplaces. Congress will likely consider other legislation to replace elements of the ACA. We do not know at this time what implications these changes and other, proposed changes, if enacted, would have on the ACA's current requirements or on our future business. Changes to the ACA or other existing health care regulations could significantly impact our business and the pharmaceutical industry.

Facilitated regulatory pathways, such as but not limited to Breakthrough Therapy Designation, Fast Track Designation, Regenerative Medicine Advanced Therapy Designation, Priority Review, Accelerated Approval, PRIME, or regulatory incentives, such as but not limited to orphan drug designation, are pathways and incentives that may not be accepted/granted, and even if granted for any of our future product candidates, may not lead to a faster development period, regulatory review or approval process, do not increase the likelihood that any of our future product candidates will receive marketing approval, and do not increase the likelihood of receiving benefits or exclusivities associated with any of these designations or pathways.

We may seek one or more facilitated regulatory pathways in the US, EU or other countries for some of our future product candidates. None of these pathways change the standards for product approval in any country. These facilitated regulatory pathways may allow for increased interaction and communication between the health authorities (e.g., FDA and EMA) and the sponsor of clinical trials, may help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens, and may allow for priority review and accelerated approval. Health authorities may not grant the requested designations, expedited pathways or other regulatory incentives. Even if granted, the receipt of the designations or the health authority support for expedited pathways or incentives may not result in a faster development process, review or approval compared to therapies considered for approval under conventional health authority procedures and does not guarantee approval in any country nor does it guarantee granting of any associated exclusivities or other benefits. In addition, even if one or more of our future product candidates qualify for any facilitated regulatory pathways or regulatory incentives, the health authority may later decide that such product candidates no longer meet the conditions for qualification, may decide that the time period for review or approval will not be shortened or may decide that the criteria for receiving exclusivity or other benefits were not adequately met.

Our development programs for our future product candidates, if any, may require substantial financial resources and may ultimately be unsuccessful.

Satisfaction of FDA and certain European regulatory requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. We believe that our cash, cash equivalents and marketable debt securities will be sufficient to fund operations for a period of at least one year from the issuance date of this Quarterly Report, but we will need to raise more funds to continue development and commercialization of our future product candidates, if any, which may not be easily available. Furthermore, we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of any future potential product candidates, such product candidates may never be approved by the FDA or other regulatory authorities.

Risks Related to Our Financial Position and Need for Capital

We have not generated any revenue from product sales. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited primarily to organizing and staffing our company and conducting research and development activities for ZGN-1061, ZGN-1258, ZGN-1345, beloranib, ZGN-839 and additional MetAP2 inhibitors. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates.

Since our inception and until July 2016, we focused substantially all of our efforts and financial resources on developing beloranib, which was in Phase 3 clinical development for our lead indication of the treatment of hyperphagia and obesity in patients with Prader Willi Syndrome and Phase 2 clinical development for the treatment of obesity in patients with hypothalamic injury-associated obesity. In December 2015, the FDA put the beloranib IND application on full clinical hold. Due to the uncertainties, costs and risks associated with the development of beloranib, in July 2016, we suspended further development of beloranib and directed our efforts and financial resources to developing ZGN-1061. In October 2016, we suspended our development of ZGN-839 in order to focus all of our resources to developing ZGN-1061 and the discovery and development of novel and highly differentiated MetAP2 inhibitors. In November 2018, we received a letter from the FDA placing a full clinical hold on our IND for the first U.S. clinical trial of ZGN-1061. The FDA cited the possibility of cardiovascular safety risks based on similar results seen in our prior compound. In July 2019, we reached agreement with the FDA on an *in vivo* animal study design and protocol to establish relevant safety margins for ZGN-1061. The study was designed to translate the data from our newly developed *in vitro* assays of human endothelial cells and assessment of tissue factor expression with endothelial cells, along with other supportive assays, as we worked toward resolving the full clinical hold. Based on the preliminary results from the *in vivo* study, on September 5, 2019, we announced that we believe there is a low probability of resolving the clinical hold in the near-term. Subsequently, all further development activities of MetAP2 inhibitors were halted and we withdrew the IND for ZGN-1061 in September 2019. Therefore, we have determined that it is in the best interest of stockholders to expand our internal corporate development efforts and formally evaluate strategic alternatives. Following an extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on December 17, 2019, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Chondrial, pursuant to which a wholly owned subsidiary of the Company will merge with and into Chondrial, with Chondrial continuing as the surviving corporation and a wholly owned subsidiary of the Company and the combined publicly traded, clinical-stage biopharmaceutical company will operate under a new name, Larimar Therapeutics, Inc. We expect to devote significant time and resources to completion of this proposed transaction.

We have funded our operations to date through proceeds from sales of redeemable convertible preferred stock, convertible debt and proceeds from our IPO and follow-on public offerings, and have incurred losses in each year since our inception. In July 2018, we sold 9,200,000 shares of our common stock at a price of $7.50 per share. Our net loss as of March 31, 2020 was $3.6 million. As of March 31, 2020, we had an accumulated deficit of $399.9 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs for ZGN-1061, ZGN-1258, ZGN-1345, beloranib, ZGN-839, early research activities, licensing milestone fees and from general and administrative costs associated with our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. In addition, if and when we obtain marketing approval for a future product candidate, we will incur significant sales, marketing and manufacturing expenses. We will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any of our product candidates, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell, our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete clinical trials that meet their clinical endpoints;
- successfully submit IND applications that go into effect with the FDA to initiate clinical trials for our future product candidates;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our future product candidates in the indications we are pursuing;
- commercialize our product candidates, if developed and approved, by developing a sales force or entering into collaborations with third parties; and
- achieve market acceptance of our product candidates in the medical community and with third-party payors.

Absent our entering into a collaboration or partnership agreement, we expect to incur significant sales and marketing costs when we prepare to commercialize our product candidates. Even if we initiate and successfully complete our clinical trials of our future product candidates, if any, and any product candidates are approved for commercial sale our product candidates, if any, may not be commercially successful drugs. Despite expending these costs, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing drugs is expensive. Depending on the status of regulatory approval or, if approved, commercialization of any of our future product candidates, as well as the progress we make in selling any of our future product candidates, we will require additional capital to fund operating needs thereafter. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our future product candidates or otherwise expand more rapidly than we anticipate.

As of March 31, 2020, our cash, cash equivalents and marketable debt securities were $63.9 million and we have a Term Loan with an outstanding principal balance of $12.7 million. The Term Loan is collateralized by substantially all of our personal property, other than our intellectual property. Additionally, we, as the borrower, are required to maintain a minimum unrestricted cash, cash equivalents and marketable debt securities balance at Silicon Valley Bank of no less than 105% of the total outstanding principal balance of the Term Loan, which as of March 31, 2020 and December 31, 2019 was $13.4 million and $15.3 million, respectively.

Further, as part of the requirements of the Term Loan, we must maintain a balance of unrestricted cash, cash equivalents and marketable debt securities at Silicon Valley Bank in an amount not less than the greater of (i) $55.0 million and (ii) sixty-five percent (65%) of all of our cash, cash equivalents and marketable debt securities. If we do not meet this requirement it will not be considered an event of default provided we immediately secure 87.5% of the principal balance in a restricted cash account. There are negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, encumbering or granting a security interest in our intellectual property, incurring indebtedness or liens, paying dividends, making certain investments, limiting the aggregate value of cash maintained by our Australian subsidiary not to exceed $4.0 million and certain other business transactions. The Term Loan also includes events of default, the occurrence and continuation of any of which provides the lenders the right to exercise remedies against us and the collateral securing the amounts due under the Term Loan, including cash in the amount of the outstanding balance. These events of default include, among other things, failure to pay any amounts due under the Term Loan, insolvency, the occurrence of a material adverse event, the occurrence of any default under certain other indebtedness and a final judgment against us in an amount greater than $0.3 million. We have estimated that the risk of subjective acceleration under the material adverse events clause is reasonably possible, however not probable and therefore have classified the outstanding principal in current and long-term liabilities based on contractually scheduled principal payments. However, the assessment of such probability of the debt holder calling the debt is subjective and their actions and/or our related assessment could change in the future, which in turn would impact the classification of the debt balances.

We expect that our cash, cash equivalents and marketable debt securities will be sufficient to fund our current operations for a period of at least one year from the issuance date of this Quarterly Report. We expect to devote significant time and resources to completion of the proposed merger with Chondrial. However, there can be no assurance that such activities will result in the completion of the Merger. Further, the completion of the Merger ultimately may not deliver the anticipated benefits or enhance shareholder value. In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our future product candidates. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. In addition, the COVID-19 pandemic and its economic impacts could adversely affect our ability to obtain financing and could affect the terms on which financing is secured. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidate or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations and strategic and licensing arrangements. On July 2, 2018, we completed a public offering of our common stock, which resulted in the sale of 9,200,000 shares at a price of $7.50 per share, resulting in net proceeds of approximately $64.6 million after deducting underwriting discounts and commissions, as well as offering costs. On November 9, 2018, we entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, with aggregate gross sales proceeds of up to $50.0 million, from time to time, through an at-the-market equity offering program under which Cowen will act as our sales agent. Through March 31, 2020 we have not sold any shares under the Sales Agreement. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, a stockholder’s ownership interest in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect the rights of our stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish rights to our future product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

Risks Related to Our Intellectual Property Rights

If we are unable to adequately protect our proprietary technology or maintain issued patents which are sufficient to protect our future product candidates, if any, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Because we expect to complete the proposed merger with Chondrial, we are not pursuing additional patents and are not continuing to maintain issued patents or other intellectual property rights in the United States and elsewhere directed to MetAP2 inhibitors. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

As of April 30, 2020, we own thirty-eight issued U.S. patents, all of which relate to our internal efforts to discover and discover MetAP2 inhibitors.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, ex parte reexamination, or inter partes review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, or comparable proceedings lodged in various foreign, both national and regional, patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our future product candidates.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our potential future sales.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our future product candidates, are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our future product candidates, our financial position and results of operations would also be materially and adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents include claims having a scope sufficient to protect our future product candidates;
- we will be able to successfully develop and commercialize any future product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- that our commercial activities or products, if any, will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing any future product candidates, if approved.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our future product candidates, if any, or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing our future product candidates, if any.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our future product candidates, if any;
- cease preparations or developing of any future product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign or rename the trademarks or trade names of our product candidates to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The U.S. Patent and Trademark Office, or U.S. PTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Issued patents covering our future product candidates, if any, could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior act, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, an April 2014 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may become dependent on licensed intellectual property for early-stage product candidates. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing such product candidates, if approved.

We had an exclusive license with Children’s Medical Center Corporation, which we elected to terminate in the first quarter of 2020, pursuant to which we exclusively licensed certain patent rights relating to decreasing the growth of fat tissue, on a worldwide basis. We may enter into additional licenses for third-party intellectual property that are necessary or useful to our business. Current or future licensors may also allege that we have breached our license agreement and may accordingly seek to terminate our license with them. In addition, current or future licensors may decide to terminate our license at will. If successful, this could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects.

We have not yet registered trademarks for a commercial trade name for our future product candidates, if any, and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for our future product candidates, if any. Any future trademark applications may be rejected during trademark registration proceedings. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the U.S. PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of development and FDA marketing approval of our future product candidates, if any, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America

Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the U.S. PTO during patent prosecution and additional procedures to attack the validity of a patent by U.S. PTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the U.S. PTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees have been previously employed, and may be employed in the future, at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize our future product candidates, which would materially adversely affect our business, financial condition and results of operations.

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

Exhibit No.	Description
2.1	Amendment No. 1 to Agreement and Plan of Merger, dated as of March 6, 2020, by and among Zafgen, Inc., Chondrial Therapeutics, Inc., Chondrial Therapeutics Holdings, LLC, and Zordich Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K filed on March 9, 2020)
3.1	Ninth Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on June 24, 2014)
3.2	Amended and Restated By-laws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrant's Form 8-K filed on June 24, 2014)
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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

		ZAFGEN, INC.
Date: May 7, 2020	By:	/s/ Jeffrey Hatfield
		Jeffrey Hatfield *Chief Executive Officer* *(Principal Executive Officer)*
Date: May 7, 2020	By:	/s/ Patricia L. Allen
		Patricia L. Allen *Chief Financial Officer* *(Principal Financial and Accounting Officer)*

Exhibit 31.1

Certification

I, Jeffrey Hatfield, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2020 of Zafgen, 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(s) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2020

/s/ Jeffrey Hatfield

Jeffrey Hatfield
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Patricia Allen, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2020 of Zafgen, 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(s) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2020

/s/ Patricia Allen
Patricia Allen
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Zafgen, Inc. (the “Company”) for the period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned officers hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to his or her knowledge:

1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 7, 2020

/s/ Jeffrey Hatfield
Jeffrey Hatfield
Chief Executive Officer
(Principal Executive Officer)

Dated: May 7, 2020

/s/ Patricia Allen
Patricia Allen
Chief Financial Officer
(Principal Financial and Accounting Officer)