UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2019

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: 001-36003

CONATUS PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-3183915**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
16745 W. Bernardo Dr., Suite 200 San Diego, CA	**92127**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 376-2600
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	CNAT	The Nasdaq Global Market

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

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

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

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

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

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

As of July 22, 2019, the registrant had 33,170,487 shares of common stock ($0.0001 par value) outstanding.

CONATUS PHARMACEUTICALS INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Conatus Pharmaceuticals Inc.
Condensed Balance Sheets
(In thousands, except par value data)
(Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 13,437	$ 11,565
Marketable securities	15,312	29,127
Collaboration receivables	3,194	3,677
Prepaid and other current assets	3,468	3,057
Total current assets	35,411	47,426
Property and equipment, net	124	154
Other assets	631	1,223
Total assets	$ 36,166	$ 48,803
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,609	$ 6,216
Accrued compensation	783	2,230
Current portion of deferred revenue	2,130	10,075
Current portion of lease liabilities	419	—
Total current liabilities	11,941	18,521
Deferred revenue, less current portion	—	2,815
Lease liabilities, less current portion	116	—
Deferred rent, less current portion	—	68
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 200,000 shares authorized; 33,170 shares issued and outstanding at June 30, 2019; 33,165 shares issued and outstanding at December 31, 2018	3	3
Additional paid-in capital	216,133	214,042
Accumulated other comprehensive income (loss)	5	(17)
Accumulated deficit	(192,032)	(186,629)
Total stockholders' equity	24,109	27,399
Total liabilities and stockholders' equity	$ 36,166	$ 48,803

See accompanying notes to condensed financial statements.

Conatus Pharmaceuticals Inc.
Condensed Statements of Operations and Comprehensive Loss
(In thousands, except per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Collaboration revenue	$ 10,791	$ 8,774	$ 17,815	$ 18,511
Total revenues	10,791	8,774	17,815	18,511
Operating expenses:				
Research and development	8,565	10,737	17,948	22,818
General and administrative	3,054	2,594	5,645	5,307
Total operating expenses	11,619	13,331	23,593	28,125
Loss from operations	(828)	(4,557)	(5,778)	(9,614)
Other income (expense):				
Interest income	172	244	372	477
Interest expense	—	(187)	—	(372)
Other income (expense)	—	3	3	(6)
Total other income	172	60	375	99
Net loss	(656)	(4,497)	(5,403)	(9,515)
Other comprehensive income (loss):				
Net unrealized gains on marketable securities	2	71	22	36
Comprehensive loss	$ (654)	$ (4,426)	$ (5,381)	$ (9,479)
Net loss per share, basic and diluted	$ (0.02)	$ (0.15)	$ (0.16)	$ (0.32)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	33,168	30,114	33,167	30,081

See accompanying notes to condensed financial statements.

Conatus Pharmaceuticals Inc.
Condensed Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2018	33,165	$ 3	$ 214,042	$ (17)	$ (186,629)	$ 27,399
Share-based compensation	—	—	926	—	—	926
Net loss	—	—	—	—	(4,747)	(4,747)
Unrealized gain on marketable securities	—	—	—	20	—	20
Balance at March 31, 2019	33,165	$ 3	$ 214,968	$ 3	$ (191,376)	$ 23,598
Issuance of common stock for employee stock purchase plan	5	—	4	—	—	4
Share-based compensation	—	—	1,161	—	—	1,161
Net loss	—	—	—	—	(656)	(656)
Unrealized gain on marketable securities	—	—	—	2	—	2
Balance at June 30, 2019	33,170	$ 3	$ 216,133	$ 5	$ (192,032)	$ 24,109
Balance at December 31, 2017	30,035	$ 3	$ 196,077	$ (77)	$ (168,007)	$ 27,996
Issuance of common stock upon exercise of stock options	28	—	37	—	—	37
Share-based compensation	—	—	983	—	—	983
Cumulative effect of adoption of accounting standard	—	—	—	—	(612)	(612)
Net loss	—	—	—	—	(5,018)	(5,018)
Unrealized loss on marketable securities	—	—	—	(35)	—	(35)
Balance at March 31, 2018	30,063	$ 3	$ 197,097	$ (112)	$ (173,637)	$ 23,351
Issuance of common stock upon exercise of stock options	66	—	66	—	—	66
Issuance of common stock for employee stock purchase plan	16	—	51	—	—	51
Share-based compensation	—	—	929	—	—	929
Net loss	—	—	—	—	(4,497)	(4,497)
Unrealized gain on marketable securities	—	—	—	71	—	71
Balance at June 30, 2018	30,145	$ 3	$ 198,143	$ (41)	$ (178,134)	$ 19,971

See accompanying notes to condensed financial statements.

Conatus Pharmaceuticals Inc.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2019	**2018**
Operating activities		
Net loss	$ (5,403)	$ (9,515)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	41	54
Stock-based compensation expense	2,087	1,912
Amortization of premiums and discounts on marketable securities, net	(162)	(127)
Accrued interest included in convertible note payable	—	372
Changes in operating assets and liabilities:		
Collaboration receivables	483	(1,486)
Prepaid and other current assets	616	277
Other assets	—	(246)
Accounts payable and accrued expenses	2,452	(334)
Accrued compensation	(1,447)	(523)
Deferred revenue	(10,760)	(7,811)
Lease liabilities, net	(27)	—
Deferred rent	—	(20)
Net cash used in operating activities	(12,120)	(17,447)
Investing activities		
Maturities of marketable securities	28,500	36,925
Purchase of marketable securities	(14,501)	(24,067)
Capital expenditures	(11)	(5)
Net cash provided by investing activities	13,988	12,853
Financing activities		
Proceeds from stock issuances related to exercise of stock options and employee stock purchase plan	4	154
Net cash provided by financing activities	4	154
Net increase (decrease) in cash and cash equivalents	1,872	(4,440)
Cash and cash equivalents at beginning of period	11,565	16,079
Cash and cash equivalents at end of period	$ 13,437	$ 11,639

See accompanying notes to condensed financial statements.

1. Organization and Basis of Presentation

Conatus Pharmaceuticals Inc. (the Company) was incorporated in the state of Delaware on July 13, 2005. The Company is a biotechnology company that has been focused on the development and commercialization of novel medicines to treat chronic diseases with significant unmet need. The Company has been developing emricasan, a first-in-class, orally active pan-caspase inhibitor, for the treatment of patients with chronic liver disease. In December 2016, the Company entered into an Option, Collaboration and License Agreement (the Collaboration Agreement) with Novartis Pharma AG (Novartis) for the development and commercialization of emricasan. As of June 30, 2019, the Company has devoted substantially all of its efforts to product development and has not realized product sales revenues from its planned principal operations.

In June 2019, the Company announced that top-line results from its ENCORE-LF clinical trial of emricasan did not meet the primary endpoint, and the Company is discontinuing further treatment of patients enrolled in the ENCORE-LF clinical trial. In addition, results from the 24-week extension in the Company's ENCORE-PH clinical trial of emricasan were consistent with results from the initial 24-week treatment period and did not meet predefined objectives. In March 2019, the Company announced that top-line results from the ENCORE-NF clinical trial of emricasan also did not meet the primary endpoint.

Consequently, the Company and Novartis have no further development plans for emricasan, and the Company plans to complete closeout activities for the clinical trials of emricasan for which it is responsible under the Collaboration Agreement. In connection with the recent emricasan clinical trial results, the Company commenced a restructuring plan in June 2019 that included reducing staff and suspending development of its inflammasome disease candidate, CTS-2090, in order to extend its resources. The Company has engaged a financial advisor to assist in the exploration and evaluation of strategic alternatives to enhance shareholder value, including a merger, an acquisition or sale of assets or a dissolution and liquidation of the Company. There can be no assurance any transaction will result from the Company's evaluation of strategic alternatives. As part of this process, the Company plans to evaluate future opportunities, if any, for emricasan and the Company's inflammasome program.

The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. The Company has experienced net losses since its inception and, as of June 30, 2019, had an accumulated deficit of $192.0 million. The Company expects to continue to incur net losses for at least the next several years. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. If the Company is unable to generate revenues adequate to support its cost structure, the Company may need to raise additional equity or debt financing or seek to complete one of the strategic alternatives described above.

The accompanying unaudited interim condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC) related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. The unaudited interim condensed financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The operating results presented in these unaudited interim condensed financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2018 included in the Company's annual report on Form 10-K filed with the SEC on March 8, 2019.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash. Additionally, the Company established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

Marketable Securities

The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the condensed balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than one year as current assets because such marketable securities are available to fund the Company's current operations. The Company invests its excess cash balances primarily in corporate debt securities and money market funds with strong credit ratings. Realized gains and losses are calculated on the specific identification method and recorded as interest income. There were no realized gains and losses for the six-month periods ended June 30, 2019 and 2018.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is other-than-temporary. The Company considers factors including: the significance of the decline in value compared to the cost basis, underlying factors contributing to a decline in the prices of securities in a single asset class, the length of time the market value of the security has been less than its cost basis, the security's relative performance versus its peers, sector or asset class, expected market volatility and the market and economy in general. When the Company determines that a decline in the fair value below its cost basis is other-than-temporary, the Company recognizes an impairment loss in the period in which the other-than-temporary decline occurred. There have been no other-than-temporary declines in the value of marketable securities, as it is more likely than not the Company will hold the securities until maturity or a recovery of the cost basis.

Fair Value of Financial Instruments

The carrying amounts of collaboration receivables, prepaid and other current assets, and accounts payable and accrued expenses are reasonable estimates of their fair value because of the short maturity of these items.

Stock-Based Compensation

Stock-based compensation expense for stock option grants under the Company's stock option plans is recorded at the estimated fair value of the award as of the grant date and is recognized as expense on a straight-line basis over the requisite service period of the stock-based award, and forfeitures are recognized as they occur. Stock-based compensation expense for employee stock purchases under the Company's 2013 Employee Stock Purchase Plan (the ESPP) is recorded at the estimated fair value of the purchase as of the plan enrollment date and is recognized as expense on a straight-line basis over the applicable six-month ESPP offering period. The estimation of stock option and ESPP fair value requires management to make estimates and judgments about, among other things, employee exercise behavior, forfeiture rates and volatility of the Company's common stock. The judgments directly affect the amount of compensation expense that will be recognized.

Property and Equipment

Property and equipment, which consists of furniture and fixtures, computers and office equipment, scientific equipment and leasehold improvements, are stated at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the lease term.

Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment, to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management's estimate of the asset's ability to generate positive income from operations and positive cash flow in future periods, as well as the strategic significance of the assets to the Company's business objective. Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount of the asset's fair value. The Company has not recognized any impairment losses through June 30, 2019.

Revenue Recognition

Under the relevant accounting literature, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. The Company performs the following five steps in order to determine revenue recognition for contracts: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the entity satisfies a performance obligation.

At contract inception, the Company identifies the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. Revenue is then recognized for the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

In a contract with multiple performance obligations, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue or expense recognition as a change in estimate.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or a collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or a collaboration partner's control, such as operational developmental milestones and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which will affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and a license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied, or partially satisfied. To date, the Company has not recognized any royalty revenue from collaborative arrangements.

In December 2016, the Company entered into the Collaboration Agreement and an Investment Agreement (the Investment Agreement) with Novartis. The Company concluded that there were two significant performance obligations under the Collaboration Agreement: the license and the research and development services, but that the license is not distinct from the research and development services as Novartis cannot obtain value from the license without the research and development services, which the Company is uniquely able to perform.

The Company concluded that progress towards completion of the performance obligations related to the Collaboration Agreement is best measured in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. The Company periodically reviews and updates the estimated collaboration expenses, when appropriate, which adjusts the percentage of revenue that is recognized for the period. While such changes to the Company's estimates have no impact on the Company's reported cash flows, the amount of revenue recorded in the period could be materially impacted. The transaction price to be recognized as revenue under the Collaboration Agreement consists of the upfront payment, option exercise fee, deemed revenue from the premium paid by Novartis under the Investment Agreement and estimated reimbursable research and development costs. Certain expenses directly related to execution of the Collaboration Agreement were capitalized as assets on the balance sheet and are being expensed in a manner consistent with the methodology used for recognizing revenue.

The Company does not expect Novartis to continue development and commercialization of emricasan and does not expect to receive any future milestone, royalty or profit and loss sharing payments under the Collaboration Agreement.

See Note 8 – Collaboration and License Agreements for further information.

Research and Development Expenses

All research and development costs are expensed as incurred.

Income Taxes

The Company's policy related to accounting for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As of December 31, 2018, there are no unrecognized tax benefits included in the condensed balance sheet that would, if recognized, affect the Company's effective tax rate, and the Company has noted no material changes through June 30, 2019. The Company has not recognized interest and penalties in the condensed balance sheets or condensed statements of operations and comprehensive loss. The Company is subject to U.S. and California taxation. As of December 31, 2018, the Company's tax years beginning 2005 to date are subject to examination by taxing authorities.

Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the condensed financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from nonowner sources, including unrealized gains and losses on marketable securities. Comprehensive gains (losses) have been reflected in the condensed statements of operations and comprehensive loss for all periods presented.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is used in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and managed its business as one segment operating primarily in the United States.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share in the periods in which they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive (in thousands):

	June 30,	
	2019	2018
Warrants to purchase common stock	13	13
Common stock options issued and outstanding	6,411	5,528
Shares issuable upon conversion of convertible note payable	—	2,846
ESPP shares pending issuance	—	6
Total	6,424	8,393

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842). This guidance requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. ASU 2016-02 establishes a right-of-use model (ROU) that requires a lessee to recognize an ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. The Company adopted this standard effective January 1, 2019, as required, retrospectively through a cumulative effect adjustment. The new standard provides a number of optional practical expedients in transition. The Company elected the "package of practical expedients," which permits the Company not to reassess, under ASU 2016-02, prior conclusions about lease identification, lease classification and initial direct costs. The new standard also provides practical expedients for an entity's ongoing accounting. The Company elected to utilize the short-term lease recognition exemption for all leases that qualify. This means, for those short-term leases that qualify, the Company will not recognize ROU assets or lease liabilities. The Company also elected not to separate lease and non-lease components for facility leases. Adoption of this guidance resulted in the recognition of lease liabilities of $0.7 million, based on the present value of the remaining minimum rental payments under current leasing standards for the Company's applicable existing office space operating lease, with corresponding ROU assets of $0.6 million.

See Note 9 – Commitments for further information.

3. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Includes financial instruments for which quoted market prices for identical instruments are available in active markets.

Level 2: Includes financial instruments for which there are inputs other than quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets with insufficient volume or infrequent transaction (less active markets) or model-driven valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.

Level 3: Includes financial instruments for which fair value is derived from valuation techniques in which one or more significant inputs are unobservable, including management's own assumptions.

Below is a summary of assets, including cash, cash equivalents and marketable securities, measured at fair value as of June 30, 2019 and December 31, 2018 (in thousands):

		Fair Value Measurements Using		
	June 30, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash	$ 2,452	$ 2,452	$ —	$ —
Money market funds	6,997	6,997	—	—
Corporate debt securities	19,300	—	19,300	—
Total	$ 28,749	$ 9,449	$ 19,300	$ —

	December 31, 2018	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash	$ 2,072	$ 2,072	$ —	$ —
Money market funds	8,000	8,000	—	—
Corporate debt securities	30,620	—	30,620	—
Total	$ 40,692	$ 10,072	$ 30,620	$ —

The Company's marketable securities, consisting principally of debt securities, are classified as available-for-sale, are stated at fair value, and consist of Level 2 financial instruments in the fair value hierarchy. The Company determines the fair value of its debt security holdings based on pricing from a service provider. The service provider values the securities based on using market prices from a variety of industry-standard independent data providers. Such market prices may be quoted prices in active markets for identical assets (Level 1 inputs) or pricing determined using inputs other than quoted prices that are observable either directly or indirectly (Level 2 inputs), such as yield curve, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, broker and dealer quotes, as well as other relevant economic measures.

4. Marketable Securities

The Company invests its excess cash in money market funds and debt instruments of financial institutions, corporations, government sponsored entities and municipalities. The following tables summarize the Company's marketable securities (in thousands):

As of June 30, 2019	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	$ 15,307	$ 5	$ —	$ 15,312
Total		$ 15,307	$ 5	$ —	$ 15,312

As of December 31, 2018	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	$ 29,144	$ —	$ (17)	$ 29,127
Total		$ 29,144	$ —	$ (17)	$ 29,127

5. Property and Equipment

Property and equipment consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Furniture and fixtures	$ 334	$ 334
Equipment	215	208
Leasehold improvements	147	147
	696	689
Less accumulated depreciation and amortization	(572)	(535)
Total	$ 124	$ 154

6. Note Payable

On February 15, 2017, the Company issued a convertible promissory note (the Novartis Note) in the principal amount of $15.0 million, pursuant to the Investment Agreement. The Novartis Note bore interest on the unpaid principal balance at a rate of 6% per annum and had a scheduled maturity date of December 31, 2019. The terms of the Novartis Note allowed the Company to convert the principal and accrued interest into the Company's common stock at a conversion price equal to 120% of the 20-day trailing average closing price per share of the common stock immediately prior to the conversion date. The ability to borrow and repay the debt at a discount using shares of the Company's common stock was deemed to be additional, foregone revenue attributable to the Collaboration Agreement, which the Company imputed and recorded as both a receivable from Novartis and a liability (deferred

revenue) of $2.5 million at the inception of the Collaboration Agreement and the Investment Agreement. On February 15, 2017, the Company recorded the $15.0 million proceeds from the issuance of the Novartis Note as a convertible note payable in the amount of $12.5 million and a reduction of the outstanding receivable from Novartis of $2.5 million. On December 5, 2018, the Company, at its option, converted the entire outstanding principal of $15.0 million and accrued and unpaid interest of the Novartis Note into 2,882,519 shares of the Company's common stock at a conversion price of $5.77 per share.

The Company elected to account for the Novartis Note under the fair value option. Prior to conversion of the Novartis Note, the Company concluded that the fair value of the Novartis Note remained at $12.5 million, plus the related accrued interest, due to its conversion features. The fair value measurement was categorized within Level 2 of the fair value hierarchy.

7. Stockholders' Equity

Common Stock

On August 2, 2018, the Company entered into an At Market Issuance Sales Agreement (the Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel), pursuant to which the Company may sell from time to time, at its option, up to an aggregate of $35.0 million of shares of its common stock through Stifel, as sales agent. Sales of the Company's common stock made pursuant to the Sales Agreement, if any, will be made on The Nasdaq Global Market (Nasdaq), under the Company's Registration Statement on Form S-3 filed on August 17, 2017 and declared effective by the SEC on November 9, 2017, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, the Company may also sell shares of its common stock through Stifel, on Nasdaq or otherwise, at negotiated prices or at prices related to the prevailing market price. The Company will pay a commission rate equal to up to 3.0% of the gross sales price per share sold. As of June 30, 2019, the Company has incurred legal and accounting costs of $0.1 million related to the Sales Agreement, which are recorded in other assets on the balance sheet until such time as the Company issues shares pursuant to the Sales Agreement. As of June 30, 2019, no shares were issued pursuant to the Sales Agreement.

Warrants

In 2013, the Company issued warrants exercisable for 111,112 shares of Series B preferred stock, at an exercise price of $0.90 per share, to Oxford Finance LLC and Silicon Valley Bank in conjunction with the Company's entry into a loan and security agreement (the Lender Warrants). Upon completion of the Company's initial public offering, the Lender Warrants became exercisable for 13,468 shares of common stock at an exercise price of $7.43 per share. The Lender Warrants will expire on July 3, 2023.

Stock Options

The following table summarizes the Company's stock option activity under all stock option plans for the six months ended June 30, 2019 (options in thousands):

	Total Options	Weighted-Average Exercise Price
Balance at December 31, 2018	5,385	$ 5.20
Granted	1,694	1.87
Exercised	—	—
Forfeited/cancelled/expired	(668)	4.04
Balance at June 30, 2019	6,411	$ 4.44

Stock-Based Compensation

The Company recorded stock-based compensation of $1.2 million and $0.9 million for the three months ended June 30, 2019 and 2018, respectively, and $2.1 million and $1.9 million for the six months ended June 30, 2019 and 2018, respectively.

Common Stock Reserved for Future Issuance

The following shares of common stock were reserved for future issuance at June 30, 2019 (in thousands):

Warrants to purchase common stock	13
Common stock options issued and outstanding	6,411
Common stock authorized for future option grants	818
Common stock authorized for the ESPP	490
Total	7,732

8. Collaboration and License Agreements

In December 2016, the Company entered into the Collaboration Agreement, pursuant to which the Company granted Novartis an exclusive option to collaborate with the Company to develop products containing emricasan. Pursuant to the Collaboration Agreement, the Company received a non-refundable upfront payment of $50.0 million from Novartis.

In May 2017, Novartis exercised its option under the Collaboration Agreement. In July 2017, the Company received a $7.0 million option exercise payment, at which time the license under the Collaboration Agreement became effective (the License Effective Date). Under the Collaboration Agreement, the Company is eligible to receive up to an aggregate of $650.0 million in milestone payments over the term of the Collaboration Agreement, contingent on the achievement of certain development, regulatory and commercial milestones, as well as royalties or profit and loss sharing on future product sales in the United States, if any.

Novartis will generally pay 50% of the Company's Phase 2b and observational study costs pursuant to an agreed upon budget. Upon completion of the ongoing Phase 2b trials, Novartis will assume 100% of the observational study costs. Novartis will assume full responsibility for emricasan's Phase 3 development and all combination product development. The Company and Novartis have no further development plans for emricasan. Therefore, the Company does not expect to receive any future milestone, royalty or profit and loss sharing payments under the Collaboration Agreement.

Unless terminated earlier, the Collaboration Agreement will remain in effect on a product-by-product and country-by-country basis until Novartis' royalty obligations expire. Novartis has certain termination rights in the event of a mandated clinical trial hold for any product containing emricasan as its sole active ingredient. Additionally, Novartis has the right to terminate the Collaboration Agreement without cause upon 180 days prior written notice to the Company. In such event, the license granted to Novartis will be terminated and revert to the Company. In the event Novartis terminates the Collaboration Agreement due to the Company's uncured material breach or insolvency, the license granted to Novartis pursuant to the Collaboration Agreement will become irrevocable, and Novartis will be required to continue to make all milestone and royalty payments otherwise due to the Company under the Collaboration Agreement, provided that if the Company materially breaches the Collaboration Agreement such that the rights licensed to Novartis or the commercial prospects of the emricasan products are seriously impaired, the milestone and royalty payments will be reduced by 50%.

Concurrent with entry into the Collaboration Agreement, the Company entered into the Investment Agreement, whereby the Company was able to borrow up to $15.0 million at a rate of 6% per annum, under one or two notes, with a maturity date of December 31, 2019. On February 15, 2017, the Company issued the Novartis Note in the principal amount of $15.0 million pursuant to the Investment Agreement. The terms of the Novartis Note allowed the Company to convert the principal and accrued interest into the Company's common stock at a conversion price equal to 120% of the 20-day trailing average closing price per share of the common stock immediately prior to the conversion date. On December 5, 2018, the Company, at its option, converted the entire outstanding principal of $15.0 million and accrued and unpaid interest of the Novartis Note into 2,882,519 shares of the Company's common stock at a conversion price of $5.77 per share.

Under the Collaboration Agreement, there are two significant performance obligations: the license and the research and development services, but the license is not distinct from the research and development services as Novartis cannot obtain value from the license without the research and development services, which the Company is uniquely able to perform. The Company concluded that progress towards completion of the performance obligations related to the Collaboration Agreement is best measured in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. The transaction price to be recognized as revenue under the Collaboration Agreement consists of the upfront payment, option exercise fee, deemed revenue from the premium paid by Novartis under the Investment Agreement and estimated reimbursable research and development costs. Certain expenses directly related to execution of the Collaboration Agreement were capitalized as assets on the balance sheet and are being expensed in a manner consistent with the methodology used for recognizing revenue.

In connection with emricasan failing to meet the primary endpoints in the ENCORE clinical trials, the Company is discontinuing its ongoing emricasan clinical trials, resulting in a shortened timeline and reduced estimated costs related to completion of emricasan activities. During the three months ended June 30, 2019, the Company significantly reduced the total estimated collaboration expenses related to the Collaboration Agreement, which is used as the measure of progress for recognition of revenue related to the Collaboration Agreement, from the prior estimate as of March 31, 2019.Consequently, during the three months ended June 30, 2019, the Company significantly reduced the transaction price related to the Collaboration Agreement from the prior estimate as of March 31, 2019, to reflect lower estimated reimbursable research and development costs. The net effect of these changes was a cumulative catch-up in revenue of $4.6 million, which was recorded as revenue as a change in estimate during the three months ended June 30, 2019. Execution costs related to the Collaboration Agreement were similarly affected, resulting in a cumulative catch-up in operating expenses of $0.1 million.

A reconciliation of the opening and closing balances of deferred revenue related to the Collaboration Agreement, which represents the unrecognized balance of the transaction price, is as follows (in thousands):

	Deferred Revenue
Balance at December 31, 2018	$ 12,890
Additions to deferred revenue	7,055
Revenue recognized	(17,815)
Balance at June 30, 2019	$ 2,130

The Company expects to recognize deferred revenue related to the Collaboration Agreement within one year.

A reconciliation of the opening and closing balances of deferred costs related to execution of the Collaboration Agreement is as follows (in thousands):

	Deferred Costs
Balance at December 31, 2018	$ 310
Costs recognized	(259)
Balance at June 30, 2019	$ 51

The Company expects to recognize deferred costs related to execution of the Collaboration Agreement within one year.

9. Commitments

Leases

The Company determines if an arrangement is a finance lease, operating lease or short-term lease at inception, or as applicable, and accounts for the arrangement under the relevant accounting literature. Currently, the Company is only party to a non-cancelable office space operating lease and short-term lease arrangements. Under the relevant guidance, the Company recognizes operating lease ROU assets and liabilities based on the present value of the future minimum lease payments over the lease term at the commencement date, using the Company's assumed incremental borrowing rate of 12%, and amortizes the ROU assets and liabilities over the lease term. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company's short-term leases are not subject to recognition of an ROU asset or liability or straight-line lease expense requirements.

In February 2014, the Company entered into a noncancelable operating lease agreement (the Lease) for certain office space with a lease term from July 2014 through December 2019 and a renewal option for an additional five years. In May 2015, the Company entered into a first amendment to the Lease (the First Lease Amendment) for additional office space starting in September 2015 through September 2020. The First Lease Amendment also extended the term of the Lease to September 2020. The monthly base rent under the Lease and the First Lease Amendment increases approximately 3% annually from approximately $33,000 in 2015 to approximately $39,000 in 2020.

As of June 30, 2019, the Company's ROU assets and liabilities related to the Lease and the First Lease Amendment are as follows (in thousands):

ROU assets (included in other assets)	$ 436
Current portion of lease liabilities	$ 419
Lease liabilities, less current portion	116
Total lease liabilities	$ 535

The following table reconciles the undiscounted cash flows for the periods presented below to the operating lease liabilities recorded in the condensed balance sheet as of June 30, 2019 (in thousands):

Remaining in 2019	$ 221
2020	351
Total lease payments	572
Present value adjustment	(37)
Total lease liabilities	$ 535

Rent expense was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating lease	$ 94	$ 94	$ 189	$ 189
Short-term leases	19	4	36	4
Total	$ 113	$ 98	$ 225	$ 193

Other Commitments

In July 2010, the Company entered into a stock purchase agreement with Pfizer Inc. (Pfizer), pursuant to which the Company acquired all of the outstanding stock of Idun Pharmaceuticals, Inc., which was subsequently spun off to the Company's stockholders in January 2013. Under the stock purchase agreement, the Company may be required to make payments to Pfizer totaling $18.0 million upon the achievement of specified regulatory milestones.

10. Restructuring Costs

In June 2019, the Company announced a restructuring plan that included reducing staff and suspending development of its inflammasome disease candidate, CTS-2090, in order to extend the Company's resources. As a result, during the three months ended June 30, 2019, the Company recognized one-time employee severance expenses of $1.2 million, which are included in accounts payable and accrued expenses on the balance sheet, and noncash stock compensation expenses related to accelerated vesting of certain employee stock options of $0.3 million, both of which were recorded as operating expenses on the statement of operations and comprehensive loss. As of June 30, 2019, no payments have been made related to the accrued employee severance expenses of $1.2 million.

11. Subsequent Events

In August 2019, the Company effected a one-time option exchange, wherein certain employees were offered the opportunity to exchange eligible outstanding stock options with exercise prices that are significantly higher than the current fair market value of the Company's common stock for the grant of a lesser number of restricted stock units (RSU). The participants received one new RSU for every two stock options tendered for exchange. As a result, 3,200,375 stock options were exchanged for 1,600,186 RSUs. The RSUs have a one-year vesting schedule or vest upon a Change of Control, an employee's termination without Cause, or resignation for Good Reason as defined in the 2013 Incentive Award Plan. The one-time option exchange will result in additional stock compensation expense that is expected to be recorded over the one-year service term commencing August 1, 2019.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis and the unaudited interim condensed financial statements included in this quarterly report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 8, 2019.

Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important 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 the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this quarterly report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this quarterly report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors." The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

We are a biotechnology company that has been focused on the development and commercialization of novel medicines to treat chronic diseases with significant unmet need. We have been developing emricasan, a first-in-class, orally active pan-caspase inhibitor, for the treatment of patients with chronic liver disease. Emricasan is designed to reduce the activities of human caspases, which are enzymes that mediate inflammation and apoptosis. In December 2016, we entered into an Option, Collaboration and License Agreement, or the Collaboration Agreement, with Novartis Pharma AG, or Novartis, for the development and commercialization of emricasan.

In June 2019, we announced that top-line results from our ENCORE-LF clinical trial of emricasan did not meet the primary endpoint, and we are discontinuing further treatment of patients enrolled in the ENCORE-LF clinical trial. In addition, results from the 24-week extension in our ENCORE-PH clinical trial of emricasan were consistent with results from the initial 24-week treatment period and did not meet predefined objectives. In March 2019, we announced that top-line results from the ENCORE-NF clinical trial of emricasan also did not meet the primary endpoint.

Consequently, we and Novartis have no further development plans for emricasan. We plan to complete our ongoing clinical trials of emricasan for which we are responsible under the Collaboration Agreement, with such activities primarily consisting of closeout activities for the ENCORE-LF trial, and we and Novartis are in discussions for the wind-down of the collaboration.

In connection with the recent emricasan clinical trial results, we also commenced a restructuring plan in June 2019 that included reducing staff by approximately 40% and suspending development of our inflammasome disease candidate, CTS-2090, in order to extend our resources. We also engaged a financial advisor to assist in the exploration and evaluation of strategic alternatives to enhance shareholder value, including a merger, an acquisition or sale of assets or a dissolution and liquidation of the company. However, there can be no assurance any transaction will result from our evaluation of strategic alternatives.

Pursuant to the Collaboration Agreement, we granted Novartis an exclusive, worldwide license to our intellectual property rights relating to emricasan to collaborate with us for the global development and commercialization of products containing emricasan either as a single active ingredient or in combination with other Novartis compounds for liver cirrhosis or liver fibrosis for the treatment, diagnosis and prevention of disease in all indications in humans. Under the Collaboration Agreement, Novartis paid us an upfront payment of $50.0 million and the option exercise payment of $7.0 million. We are responsible for completing the three ENCORE trials and the POLT-HCV-SVR trial. We share the costs of these four Phase 2b trials equally with Novartis. In addition, until the completion of the four Phase 2b trials, we will equally share the costs of the non-treatment observational study that will follow patients from the four Phase 2b trials. After the completion of the four Phase 2b trials, Novartis will assume 100% of the observational study costs. Novartis is responsible for 100% of certain expenses for required registration-supportive nonclinical activities. Novartis is also responsible for the development of emricasan beyond the four Phase 2b trials and the observational study, for which we are responsible under the Collaboration Agreement, including the Phase 3 development of emricasan single agent products and all development for emricasan combination products, and Novartis has agreed to use commercially reasonable efforts to develop and commercialize emricasan products. However, we do not expect Novartis to continue development and commercialization of emricasan and do not expect to receive any future milestone, royalty or profit and loss sharing payments under the Collaboration Agreement.

Since our inception, our primary activities have been organizational activities, including recruiting personnel, conducting research and development, including clinical trials, and raising capital. We have no products approved for sale, and we have not generated any revenues from product sales to date. We have never been profitable and have incurred significant operating losses since our inception. We incurred net losses of $18.0 million and $17.4 million for the years ended December 31, 2018 and 2017, respectively, and $5.4 million for the six months ended June 30, 2019. As of June 30, 2019, we had an accumulated deficit of $192.0 million.

We have funded our operations since inception primarily through sales of equity securities and convertible promissory notes and payments made under the Collaboration Agreement. We expect to continue to incur significant operating losses and negative cash flows from operating activities. In May 2017, we completed a public offering of 5,980,000 shares of our common stock at a public offering price of $5.50 per share. We received net proceeds of $30.6 million, after deducting underwriting discounts and commissions and offering-related transaction costs. Immediately following the offering, we used $11.2 million of the net proceeds to repurchase and retire 2,166,836 shares of our common stock from funds affiliated with Advent Private Equity, or Advent, at a price of $5.17 per share. In August 2018, we entered into an At Market Issuance Sales Agreement, or the 2018 Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, pursuant to which we may sell from time to time, at our option, up to an aggregate of $35.0 million of shares of our common stock in “at-the-market” offerings. As of the date of the filing of this Form 10-Q, no shares have been issued pursuant to the 2018 Sales Agreement.

As of June 30, 2019, we had cash, cash equivalents and marketable securities of $28.7 million. Although it is difficult to predict future liquidity requirements, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months from the date of the filing of this Form 10-Q. We will need to raise additional capital to fund further operations. We may obtain additional financing in the future through the issuance of our common stock in future public offerings, through other equity or debt financings or through collaborations or partnerships with other companies.

Successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate sustained positive cash flow from operating activities and, unless and until we do, we will need to raise substantial additional capital through equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could have a material adverse effect on our results of operations, financial condition and our ability to execute on our business plan.

Financial Overview

Revenues

Our revenues to date have been generated primarily from the Collaboration Agreement. Under the terms of the Collaboration Agreement, we received an upfront payment of $50.0 million. In May 2017, Novartis exercised its option, and we received a $7.0 million option exercise payment in July 2017. We are eligible to receive up to $650.0 million in additional payments for development, regulatory and commercial sales milestones, as well as royalties or profit and loss sharing on future product sales in the United States, if any. However, we do not expect to receive any future milestone, royalty or profit and loss sharing payments under the Collaboration Agreement.

Under the relevant revenue recognition guidance, we recognize collaboration revenue (i.e., the transaction price) in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. We periodically review and update the total estimated collaboration expenses and the estimated transaction price, when appropriate, which adjusts the revenue recognized for the period on a cumulative catch-up basis as a change in estimate. Such changes could materially impact the amount of revenue recorded in the period.

We have no products approved for sale, and we have not generated any revenues from product sales to date. We have not submitted any product candidate for regulatory approval. If we fail to achieve clinical success for our product candidates in a timely manner and/or obtain regulatory approval forsuch product candidates, or to successfully develop other product candidates, our ability to generate future revenues would be materially adversely affected. We have no further clinical development plans for emricasan other than completing the clinical trials for which we are responsible under the Collaboration Agreement, and we are not currently developing any other product candidates.

Research and Development Expenses

The majority of our operating expenses to date have been incurred in research and development activities. Starting in late 2011, research and development expenses have been focused on the development of emricasan. Since acquiring emricasan in 2010, we have incurred $163.0 million of research and development expenses in the development of emricasan through June 30, 2019. Our business model has been focused on the development of emricasan in various liver diseases in collaboration with Novartis and the development of CTS-2090 for diseases involving inflammasome pathways. Our research and development expenses consist primarily of:

- expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our clinical trials and our preclinical studies;
- employee-related expenses, which include salaries and benefits;
- the cost of finalizing our chemistry, manufacturing and controls, or CMC, capabilities and providing clinical trial materials; and
- costs associated with other research activities and regulatory approvals.

Research and development costs are expensed as incurred.

Clinical development timelines, the probability of success and development costs can differ materially from expectations. The costs of clinical trials may vary significantly over the life of a project owing to factors that include but are not limited to the following:

- per patient trial costs;
- the number of patients that participate in the clinical trials;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

Research and development expenditures will continue to be significant as we continue closeout activities of emricasan, primarily consisting of closeout activities for the ENCORE-LF trial, through the end of 2019. We do not expect emricasan to be commercially available, if at all, for at least the next several years based on its clinical trial results.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development and administrative functions. Other general and administrative expenses include costs related to being a public company, as well as insurance, facilities, travel, patent filing and maintenance, legal and consulting expenses.

Interest Income

Interest income consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists of accrued interest on our $15.0 million convertible promissory note payable to Novartis, or the Novartis Note, which was issued in February 2017 and converted, at our option, into shares of our common stock in December 2018.

Other Income (Expense)

Other income (expense) includes non-operating transactions such as those caused by currency fluctuations between transaction dates and settlement dates.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

There were no significant changes during the six months ended June 30, 2019 to the critical accounting policies described in "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the SEC on March 8, 2019.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

Total Revenues

Total revenues were $10.8 million for the three months ended June 30, 2019, as compared to $8.8 million for the same period in 2018. The increase of $2.0 million was primarily due to the following: (i) a net cumulative catch-up in revenue recognized under the Collaboration Agreement related to a reduction in the estimated total collaboration expenses resulting in an increase in the percentage of completion under the Collaboration Agreement, net of a reduction in the transaction price due to a decrease in the estimated total reimbursable expenses under the Collaboration Agreement, (ii) partially offset by lower revenues under the Collaboration Agreement due to lower emricasan-related research and development expenses.

Research and Development Expenses

Research and development expenses were $8.6 million for the three months ended June 30, 2019, as compared to $10.7 million for the same period in 2018. The decrease of $2.1 million was primarily due to lower spending related to our ENCORE-PH and ENCORE-NF clinical trials and lower personnel costs, partially offset by recognition of severance and noncash stock compensation costs for research and development employees related to our restructuring plan announced in June 2019.

General and Administrative Expenses

General and administrative expenses were $3.1 million for the three months ended June 30, 2019, as compared to $2.6 million for the same period in 2018. The increase of $0.5 million was primarily due to recognition of severance and noncash stock compensation costs for general and administrative employees related to our restructuring plan announced in June 2019, partially offset by lower personnel costs.

Changes in components of Other Income (Expense) were as follows:

Interest Income

Interest income was $172,000 for the three months ended June 30, 2019, as compared to $244,000 for the same period in 2018. Interest income consisted of interest earned on our cash, cash equivalents and marketable securities and fluctuates based on changes in investment balances and interest rates.

Interest Expense

Interest expense was $0 for the three months ended June 30, 2019, as compared to $187,000 for the same period in 2018. The decrease was due to lower interest expense related to the Novartis Note, which was converted, at our option, into shares of our common stock in December 2018.

Other Income (Expense)

Other income was $0 for the three months ended June 30, 2019, as compared to $3,000 for the same period in 2018. Other income (expense) represents non-operating transactions such as those caused by currency fluctuations between transaction dates and settlement dates.

Comparison of the Six Months Ended June 30, 2019 and 2018

Total Revenues

Total revenues were $17.8 million for the six months ended June 30, 2019, as compared to $18.5 million for the same period in 2018. The decrease of $0.7 million was primarily due to the following: (i) lower revenues under the Collaboration Agreement due to lower emricasan-related research and development expenses, (ii) partially offset by a net cumulative catch-up in revenue recognized under the Collaboration Agreement related to a reduction in the estimated total collaboration expenses resulting in an increase in the percentage of completion under the Collaboration Agreement, net of a reduction in the transaction price due to a decrease in the estimated total reimbursable expenses under the Collaboration Agreement.

Research and Development Expenses

Research and development expenses were $17.9 million for the six months ended June 30, 2019, as compared to $22.8 million for the same period in 2018. The decrease of $4.9 million was primarily due to lower spending related to our ENCORE-PH and ENCORE-NF clinical trials, manufacturing and preclinical activities, and lower personnel costs, partially offset by higher spending related to our ENCORE-LF clinical trial and recognition of severance and noncash stock compensation costs for research and development employees related to our restructuring plan announced in June 2019.

General and Administrative Expenses

General and administrative expenses were $5.6 million for the six months ended June 30, 2019, as compared to $5.3 million for the same period in 2018. The increase of $0.3 million was primarily due to recognition of severance and noncash stock compensation costs for general and administrative employees related to our restructuring plan announced in June 2019, partially offset by lower personnel costs.

Changes in components of Other Income (Expense) were as follows:

Interest Income

Interest income was $372,000 for the six months ended June 30, 2019, as compared to $477,000 for the same period in 2018. Interest income consisted of interest earned on our cash, cash equivalents and marketable securities and fluctuates based on changes in investment balances and interest rates.

Interest Expense

Interest expense was $0 for the six months ended June 30, 2019, as compared to $372,000 for the same period in 2018. The decrease was due to lower interest expense related to the Novartis Note, which was converted, at our option, into shares of our common stock in December 2018.

Other Income (Expense)

Other income was $3,000 for the six months ended June 30, 2019, as compared to other expense of $6,000 for the same period in 2018. Other income (expense) represents non-operating transactions such as those caused by currency fluctuations between transaction dates and settlement dates.

Liquidity and Capital Resources

Since inception, we have incurred losses and negative cash flows from operating activities, except for the year ended December 31, 2016, where we had positive net cash flows from operating activities due to the upfront payment related to the Collaboration Agreement. As of June 30, 2019, we had an accumulated deficit of $192.0 million. We anticipate that we will continue to incur net losses as we continue closeout activities of emricasan and evaluate strategic alternatives to enhance shareholder value.

Prior to our initial public offering, or IPO, in July 2013, we funded our operations primarily through private placements of equity and convertible debt securities. In July 2013, we completed our IPO of 6,000,000 shares of common stock at an offering price of $11.00 per share. We received net proceeds of $58.6 million, after deducting underwriting discounts and commissions and offering-related transaction costs.

In August 2014, we entered into an At Market Issuance Sales Agreement, or the 2014 Sales Agreement, with MLV & Co. LLC, or MLV, pursuant to which we could sell from time to time, at our option, up to an aggregate of $50.0 million of shares of our common stock through MLV, as sales agent. We terminated the 2014 Sales Agreement in December 2016. We sold 6,305,526 shares of our common stock pursuant to the 2014 Sales Agreement at a weighted average price per share of $2.35 and received net proceeds of $14.2 million, after deducting offering-related transaction costs and commissions.

In April 2015, we completed a public offering of 4,025,000 shares of our common stock at a public offering price of $5.75 per share. We received net proceeds of $21.4 million, after deducting underwriting discounts and commissions and offering-related transaction costs. In May 2017, we completed a public offering of 5,980,000 shares of our common stock at a public offering price of $5.50 per share. We received net proceeds of $30.6 million, after deducting underwriting discounts and commissions and offering-related transaction costs. Immediately following the offering, we used $11.2 million of the net proceeds to repurchase and retire 2,166,836 shares of our common stock from Advent at a price of $5.17 per share, which is equal to the net proceeds per share we received from the offering, before expenses, pursuant to a stock purchase agreement we entered into with Advent in May 2017.

In December 2016, we entered into the Collaboration Agreement, pursuant to which we granted Novartis an exclusive option to collaborate with us for the global development and commercialization of emricasan. Under the Collaboration Agreement, Novartis paid us an upfront payment of $50.0 million. In May 2017, Novartis exercised its option, and we received a $7.0 million option exercise payment in July 2017. Concurrent with the entry into the Collaboration Agreement, we entered into an Investment Agreement with Novartis, or the Investment Agreement, whereby we agreed to sell and Novartis agreed to purchase, convertible promissory notes, in one or two closings, for an aggregate principal amount of up to $15.0 million. In February 2017, we issued the Novartis Note in the principal amount of $15.0 million, pursuant to the Investment Agreement. The maturity date of the Novartis Note was December 31, 2019, and it bore interest on the unpaid principal balance at a rate of 6% per annum. In December 2018, we, at our option, converted the entire outstanding principal of $15.0 million and accrued and unpaid interest of the Novartis Note into 2,882,519 shares of our common stock. Pursuant to the terms of the Novartis Note, the principal and accrued and unpaid interest converted into shares of our common stock at a conversion price equal to 120% of the 20-day trailing average closing price per share of the common stock immediately prior to the conversion date.

On August 2, 2018, we entered into the 2018 Sales Agreement, pursuant to which we may sell from time to time, at our option, up to an aggregate of $35.0 million of shares of our common stock through Stifel, as sales agent. Sales of our common stock made pursuant to the 2018 Sales Agreement, if any, will be made on The Nasdaq Global Market, or Nasdaq, under our Registration Statement on Form S-3 filed on August 17, 2017 by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the 2018 Sales Agreement, we may also sell shares of our common stock through Stifel, on Nasdaq or otherwise, at negotiated prices or at prices related to the prevailing market price. We will pay a commission rate equal to up to 3.0% of the gross sales price per share sold. The 2018 Sales Agreement will automatically terminate upon the sale of an aggregate of $35.0 million of shares of our common stock pursuant to the 2018 Sales Agreement. In addition, the 2018 Sales Agreement may be terminated by us or Stifel at any time upon ten days' notice to the other party, or by Stifel at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations. As of the date of the filing of this Form 10-Q, we have not sold any shares under the 2018 Sales Agreement.

On May 29, 2019, we received a letter from the Nasdaq staff indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until November 25, 2019, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5450(a)(1) if at any time before November 25, 2019, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days.

At June 30, 2019, we had cash, cash equivalents and marketable securities of $28.7 million. We believe our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months from the date of the filing of this Form 10-Q. To fund further operations, we will need to raise additional capital. We plan to continue to fund losses from operations and capital funding needs through future equity and debt financing, as well as potential collaborations or partnerships with other companies. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. No assurances can be provided that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs.We have engaged a financial advisor to assist in the exploration and evaluation of strategic alternatives to enhance shareholder value, including a merger, an acquisition or sale of assets or a dissolution and liquidation of the company. A strategic transaction would also likely result in substantial dilution to our stockholders and could result in other restrictions that may affect our business. Any of these actions could materially harm our business, results of operations and future prospects.

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	$ (12,120)	$ (17,447)
Net cash provided by investing activities	13,988	12,853
Net cash provided by financing activities	4	154
Net increase (decrease) in cash and cash equivalents	$ 1,872	$ (4,440)

Net cash used in operating activities was $12.1 million and $17.4 million for the six months ended June 30, 2019 and 2018, respectively. The primary use of cash was to fund our operations related to the development of emricasan, as well as internally developed product candidates, including CTS-2090.

Net cash provided by investing activities was $14.0 million and $12.9 million for the six months ended June 30, 2019 and 2018, respectively, which consisted primarily of proceeds from maturities of marketable securities, partially offset by cash used to purchase marketable securities.

Net cash provided by financing activities was $4,000 for the six months ended June 30, 2019. Net cash provided by financing activities was $154,000 for the six months ended June 30, 2018, which consisted primarily of proceeds from stock issuances related to the exercise of stock options and the employee stock purchase plan.

Contractual Obligations and Commitments

As of June 30, 2019, there have been no material changes outside the ordinary course of our business to the contractual obligations we reported in “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments” in our annual report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 8, 2019.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 4. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this quarterly report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Inherent Limitations of Disclosure Controls and Procedures and Internal Control Over Financial Reporting

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended June 30, 2019, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are currently not a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors included in "Item 1A. Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 8, 2019, other than the risk factors below.

Risks Related to Our Evaluation of Strategic Alternatives

Our activities to evaluate and pursue strategic alternatives may not be successful.

In June 2019, we announced that top-line results from our ENCORE-LF clinical trial of emricasan did not meet the primary endpoint, and we are discontinuing further treatment of patients enrolled in the ENCORE-LF clinical trial. In addition, results from the 24-week extension in our ENCORE-PH clinical trial of emricasan were consistent with results from the initial 24-week treatment period and did not meet predefined objectives. Previously, in March 2019, we announced that top-line results from the Phase 2b ENCORE-NF clinical trial of emricasan also did not meet the primary endpoint. Consequently, we and Novartis have no further development plans for emricasan. We plan to complete closeout activities for the clinical trials of emricasan for which we are responsible under an Option, Collaboration and License Agreement, or the Collaboration Agreement, with Novartis Pharma AG, or Novartis, that we entered into in December 2016. We and Novartis are in discussions for the wind-down of the collaboration. In connection with the recent emricasan clinical trial results, we also commenced a restructuring plan in June 2019 that included reducing staff by approximately 40% and suspending development of our inflammasome disease candidate, CTS-2090, in order to extend our resources.

We have engaged a financial advisor to assist in the exploration and evaluation of strategic alternatives to enhance shareholder value, including a merger, an acquisition or sale of assets or a dissolution and liquidation of the company. There can be no assurance that our process to identify and evaluate potential strategic alternatives will result in any definitive offer to consummate a strategic transaction, or if made, what the terms thereof will be or that any transaction will be approved or consummated. In addition, potential strategic transactions that require stockholder approval may not be approved by our stockholders. A strategic transaction would also likely result in substantial dilution to our stockholders and could result in other restrictions that may affect our business. Further, any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance stockholder value.

We also may acquire additional businesses, products or product candidates. Integrating any newly acquired business, product or product candidate could be expensive and time-consuming. We may not be able to integrate any acquired business, product or product candidate successfully. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses.

Any strategic transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- the inability to retain key employees of our company or any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any strategic transactions of the nature described above. Any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, financial condition and prospects.

If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. 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 process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we complete development activities under the Collaboration Agreement and evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, 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. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations, including those under the Collaboration Agreement; (ii) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iv) non-cancelable facility lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its 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 of our company.

We are substantially dependent on our remaining employees to facilitate the consummation of a strategic transaction. We could lose such key employees, in particular, as a result of the recent emricasan trial results and the restructuring plan we commenced in June 2019.

In June 2019, we commenced a restructuring plan that included reducing staff by approximately 40% and suspending development of our inflammasome disease candidate, CTS-2090, in order to extend our resources. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to evaluate and pursue strategic alternatives, as well as fulfill our reporting obligations as a public company.

We conduct our operations at our leased facility in San Diego, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is very intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, and the ability to retain our key employees is critical to our ability to effectively manage our resources and to consummate a strategic transaction. Although we are completing clinical trial closeout activities for emricasan and have suspended development of CTS-2090, if we resume the development of emricasan, CTS-2090 or new therapeutic products, such development requires expertise from a number of different disciplines, some of which are not widely available. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede our ability to identify and execute on a strategic path forward.

Our key employees have a significant amount of know-how and experience in our company, and the loss of one or more of them could have a material and adverse effect on our operations or ability to consummate a strategic transaction.

In order to induce valuable employees to remain with our company, in addition to salary and cash incentives, we have provided equity options that vest over time. In August 2019, we effected a one-time option exchange, wherein certain employees were offered the opportunity to exchange eligible outstanding stock options with exercise prices that are significantly higher than the current fair market value of our common stock for the grant of a lesser number of restricted stock units, or RSUs. The participants received one new RSU for every two stock options tendered for exchange. The value to employees of the RSUs may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies, particularly in light of the recent emricasan trial results and restructuring plan.

The loss of the services of existing personnel or the failure to recruit additional, suitable key scientific, managerial, clinical, regulatory, operational and other personnel in a timely manner could harm our business. We may experience difficulty in hiring and retaining highly-skilled employees with appropriate qualifications as needed, particularly in light of the recent emricasan trial results. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects and our ability to consummate a strategic transaction would be harmed.

Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Risks Related to Our Business and Industry

Our business is dependent on the success of a single clinical-stage product candidate, emricasan, which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales.

Our future success depends on our ability to obtain regulatory approval for, and then successfully commercialize, our only clinical-stage product candidate, emricasan. We have not completed the development of any product candidates. We generate no revenues from sales of any drugs, and we may never be able to develop a marketable drug. Emricasan will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We entered into the Collaboration Agreement with Novartis pursuant to which we granted Novartis an exclusive license to collaborate with us to develop products containing emricasan either as a single active ingredient or in combination with other Novartis compounds for liver cirrhosis or liver fibrosis. Novartis is responsible for Phase 3 development of emricasan single agent products and all development for emricasan combination products as well as the manufacturing and commercialization for all emricasan products. Neither we, nor Novartis, are permitted to market or promote emricasan before emricasan receives regulatory approval from the United States Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, and emricasan may never receive such regulatory approvals.

In June 2019, we announced that top-line results from our ENCORE-LF clinical trial of emricasan did not meet the primary endpoint, and we are discontinuing further treatment of patients enrolled in the ENCORE-LF clinical trial. In addition, results from the 24-week extension in our ENCORE-PH clinical trial of emricasan were consistent with results from the initial 24-week treatment period and did not meet predefined objectives. Previously, in March 2019, we announced that top-line results from the Phase 2b ENCORE-NF clinical trial of emricasan also did not meet the primary endpoint. Consequently, we and Novartis have no further development plans for emricasan. We plan to complete closeout activities for the clinical trials of emricasan for which we are responsible under the Collaboration Agreement, and we and Novartis are in discussions for the wind-down of the collaboration. However, we cannot assure you that we will or will not pursue emricasan development if the Novartis collaboration ends.

If we do continue clinical development of emricasan, there is no guarantee that our current or future clinical trials will be completed on time or at all or that any future clinical trials will commence on time or at all, and the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials. Even if such regulatory authorities agree with the design and implementation of our clinical trials, we cannot guarantee you that such regulatory authorities will not change their requirements in the future. In addition, even if our clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials would likely be required before we submit emricasan for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of emricasan may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of emricasan.

We cannot anticipate when or if we will seek regulatory review of emricasan for any indication. We have not previously submitted a new drug application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. An NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process and may not be obtained. We have not received marketing approval for any product candidate, and we cannot be certain that emricasan will be successful in future clinical trials or receive regulatory approval for any indication. If we do not receive regulatory approvals for and successfully commercialize emricasan on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market emricasan, our revenues will be dependent on the ability to commercialize emricasan as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for the treatment of NASH, including NASH cirrhosis or NASH fibrosis, are not as significant as we estimate, our business and prospects will be harmed. Furthermore, given the recent emricasan trial results in NASH, we cannot assure you that emricasan will be successful in future clinical trials or as a commercial product for NASH.

If we resume the development of any product candidates, additional capital that we may need to operate or expand our business may not be available.

We may require additional capital to operate or expand our business. The failure of emricasan in recent trials to meet the primary endpoints may make it very difficult for us to seek and obtain financing from the capital markets on favorable terms, or at all. If we raise additional funds through the issuance of equity or convertible securities, the percentage ownership of holders of our common stock could be substantially diluted, and these newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. Furthermore, volatility in the credit or equity markets may have an adverse effect on our ability to obtain debt or equity financing or the cost of such financing. If we do not have funds available to enhance any potential product candidates, maintain the competitiveness of our technology and pursue business opportunities, this could have an adverse effect on our business, operating results and financial condition.

Risks Related to Our Reliance on Third Parties

If Novartis terminates the Collaboration Agreement, we may not receive additional payments under the Collaboration Agreement, and we may not be able to enter into a similar agreement on favorable terms, or at all.

Pursuant to the Collaboration Agreement, Novartis has certain termination rights in the circumstances of an uncured material breach or insolvency by us and in the event of a mandated clinical trial hold for any products containing only emricasan as an active ingredient, or Emricasan Only Products. Additionally, Novartis has the right to terminate the Collaboration Agreement without cause upon 180 days prior written notice to us. In such event, the license granted to Novartis will be terminated and revert to us, and Novartis will transfer any ongoing trials for the Emricasan Only Products to us and will cease development of emricasan products. In the event Novartis terminates the Collaboration Agreement due to our uncured material breach or insolvency, the license granted to Novartis pursuant to the Collaboration Agreement will become irrevocable, and Novartis will be required to continue to make all milestone and royalty payments otherwise due to us under the Collaboration Agreement, provided that if we materially breach the Collaboration Agreement such that the rights licensed to Novartis or the commercial prospects of emricasan products are seriously impaired, the milestone and royalty payments will be reduced by 50 percent.

In June 2019, we announced that top-line results from our ENCORE-LF clinical trial of emricasan did not meet the primary endpoint, and we are discontinuing further treatment of patients enrolled in the ENCORE-LF clinical trial. In addition, results from the 24-week extension in our ENCORE-PH clinical trial of emricasan were consistent with results from the initial 24-week treatment period and did not meet predefined objectives. Previously, in March 2019, we announced that top-line results from the Phase 2b ENCORE-NF clinical trial of emricasan also did not meet the primary endpoint. Consequently, we and Novartis have no further development plans for emricasan. We plan to complete closeout activities for the clinical trials of emricasan for which we are responsible under the Collaboration Agreement, and we and Novartis are in discussions for the wind-down of the collaboration.

If Novartis terminates the Collaboration Agreement, we will not receive additional milestones under the Collaboration Agreement, and we may be unable to raise the additional capital required to further develop and commercialize emricasan or enter into a collaboration agreement with another pharmaceutical compan y with equivalent or comparable terms, or at all. Further, any delays in entering into new strategic partnership agreements related to emricasan could delay the development and commercialization of emricasan, which would harm our business, prospects, financial condition and results of operations. In addition, a strategic transaction may not result in any future development and commercialization of emricasan, which would harm our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Requirements

To conserve capital, we may undertake additional workforce and cost reduction activities in the future. These activities may cause us to be unable to fully support and manage our operations.

In June 2019, we implemented a restructuring plan to conserve capital, and we may, in the future, need to undertake additional workforce reductions or restructuring activities. As a result of the reduction in our workforce, we face an increased risk of employment litigation. We also need to effectively manage our operations and facilities. Following our recent workforce reduction in June 2019, it is possible that our infrastructure may be inadequate to support our future efforts and business strategy or to maintain operational, financial and management controls and reporting systems and procedures. If we cannot successfully manage our operations, we may be unsuccessful in executing our business strategy, including potential strategic alternatives.

Risks Related to Ownership of our Common Stock

If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Capital Market, our common stock could be delisted.

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, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

On May 29, 2019, we received a letter from the Nasdaq staff indicating that, for the last thirty consecutive business days, the bid price forour common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until November 25, 2019, to regain compliance. The letter stated that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5450(a)(1) if at any time before November 25, 2019, the bid price ofour common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter has no immediate effect on the listing or trading of our common stock, and our common stock will continue to trade on The Nasdaq Global Market under the symbol "CNAT." We intend to monitor the bid price of our common stock and consider available options if our common stock does not trade at a level likely toresult in our regaining compliance with The Nasdaq Global Market's minimum bid price rule by November 25, 2019.

If we do not regain compliance with Rule 5450(a)(1) by November 25, 2019, 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 Global 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 Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, the Nasdaq staff would notify us that our securities would be subject to delisting. In the event of such a notification, we may appeal the Nasdaq staff's determination to delist our securities, but there can be no assurance the Nasdaq staff would grant our request for continued listing.

In the event that our common stock is delisted from The Nasdaq Global Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only 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 securities 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 we are not listed on a major exchange.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

A list of exhibits is set forth on the Exhibit Index immediately preceding the signature page of this quarterly report on Form 10-Q and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
4.1(2)	Specimen Common Stock Certificate
4.2(3)	First Amended and Restated Investor Rights Agreement, dated February 9, 2011
4.3(2)	Form of Warrant issued to lenders under the Loan and Security Agreement, dated July 3, 2013, by and among the Registrant, Oxford Finance LLC, Silicon Valley Bank and the other lenders party thereto
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer 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 Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 1, 2013.
(2) Incorporated by reference to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (Registration No. 333-189305), filed with the SEC on July 8, 2013.
(3) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (Registration No. 333-189305), filed with the SEC on June 14, 2013.
* This certification is being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CONATUS PHARMACEUTICALS INC.

Date: August 7, 2019

/s/ Steven J. Mento, Ph.D.
Steven J. Mento, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: August 7, 2019

/s/ Keith W. Marshall, Ph.D.
Keith W. Marshall, Ph.D.
Executive Vice President, Chief Operating Officer and Chief Financial Officer
(principal financial officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven J. Mento, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Conatus Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 7, 2019

/s/ Steven J. Mento, Ph.D.
Steven J. Mento, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Keith W. Marshall, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Conatus Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 7, 2019

/s/ Keith W. Marshall, Ph.D.
Keith W. Marshall, Ph.D.
Executive Vice President, Chief Operating Officer and Chief Financial Officer
(principal financial 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 of Conatus Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven J. Mento, Ph.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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.

Date: August 7, 2019

/s/ Steven J. Mento, Ph.D.
Steven J. Mento, Ph.D.
President and Chief Executive Officer
(principal executive officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

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 of Conatus Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith W. Marshall, Ph.D., Executive Vice President, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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.

Date: August 7, 2019

/s/ Keith W. Marshall, Ph.D.
Keith W. Marshall, Ph.D.
Executive Vice President, Chief Operating Officer and Chief Financial Officer
(principal financial officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.