Conatus Pharmaceuticals Inc. Form 10-Q May 03, 2019

**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 MARCH 31, 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 (I.R.S. Employer

Incorporation or Organization) 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)

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.

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

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

Title of each class
Common Stock, par value \$0.0001 per share

CNAT
The Nasdaq Global Market

As of April 22, 2019, the registrant had 33,165,122 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)

	March 31, 2019	December 31, 2018
Assets	2017	2010
Current assets:		
Cash and cash equivalents	\$19,168	\$ 11,565
Marketable securities	14,665	29,127
Collaboration receivables	3,860	3,677
Prepaid and other current assets	2,633	3,057
Total current assets	40,326	47,426
Property and equipment, net	145	154
Other assets	1,707	1,223
Total assets	\$42,178	\$ 48,803
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$7,292	\$ 6,216
Accrued compensation	935	2,230
Current portion of deferred revenue	8,150	10,075
Current portion of lease liabilities	398	_
Total current liabilities	16,775	18,521
Deferred revenue, less current portion	1,576	2,815
Lease liabilities, less current portion	229	_
Deferred rent, less current portion		68
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized; no shares issued and		
outstanding	<del></del>	_
Common stock, \$0.0001 par value; 200,000 shares authorized; 33,165 shares issued		
and outstanding at March 31, 2019; 33,165 shares issued and outstanding at		
December 31, 2018	3	3
Additional paid-in capital	214,968	214,042

Accumulated other comprehensive income (loss)	3	(17	)
Accumulated deficit	(191,376)	(186,629	)
Total stockholders' equity	23,598	27,399	
Total liabilities and stockholders' equity	\$42,178	\$ 48,803	

See accompanying notes to condensed financial statements.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except per share data)

(Unaudited)

	Three Mo Ended Ma	
	2019	2018
Revenues:		
Collaboration revenue	\$7,024	\$9,737
Total revenues	7,024	9,737
Operating expenses:		
Research and development	9,383	12,081
General and administrative	2,591	2,713
Total operating expenses	11,974	14,794
Loss from operations	(4,950)	(5,057)
Other income (expense):		
Interest income	200	233
Interest expense	—	(185)
Other income (expense)	3	(9)
Total other income	203	39
Net loss	(4,747)	(5,018)
Other comprehensive income (loss):		
Net unrealized gains (losses) on marketable securities	20	(35)
Comprehensive loss	\$(4,727)	\$(5,053)
Net loss per share, basic and diluted	\$(0.14)	\$(0.17)
Weighted average shares outstanding used in computing net loss per share,		
basic and diluted	33,165	30,048

See accompanying notes to condensed financial statements.

Condensed Statements of Stockholders' Equity

(In thousands)

(Unaudited)

# Accumulated

			Additional	Other		Total	
	Common	Stock	Paid-in	Comprehen	asive Accumulated	Stockhold	ers'
	Shares	Amount	Capital	(Loss)	Deficit	Equity	
Balance at December 31, 2018	33,165	\$ 3	\$214,042	\$ (17	) \$ (186,629	\$ 27,399	
Share-based compensation			926		<del>-</del>	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	
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	

See accompanying notes to condensed financial statements.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Mo Ended Ma 2019	
Operating activities		
Net loss	\$(4,747)	\$(5,018)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	20	27
Stock-based compensation expense	926	983
Amortization of premiums and discounts on marketable securities, net	(94)	(55)
Accrued interest included in convertible note payable	—	185
Changes in operating assets and liabilities:		
Collaboration receivables	(183)	(2,480)
Prepaid and other current assets	453	339
Accounts payable and accrued expenses	1,133	2,678
Accrued compensation	(1,295)	(913)
Deferred revenue	(3,164)	(3,890)
Lease liabilities	(13)	
Deferred rent	_	(10)
Net cash used in operating activities	(6,964)	(8,154)
Investing activities		
Maturities of marketable securities	19,000	18,875
Purchase of marketable securities	(4,424)	(10,217)
Capital expenditures	(9)	(5)
Net cash provided by investing activities	14,567	8,653
Financing activities		
Proceeds from stock issuances related to exercise of stock options	_	37
Net cash provided by financing activities	_	37
Net increase in cash and cash equivalents	7,603	536
Cash and cash equivalents at beginning of period	11,565	16,079
Cash and cash equivalents at end of period	\$19,168	\$16,615

See accompanying notes to condensed financial statements.

Notes to Condensed Financial Statements

(Unaudited)

# 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 focused on the development and commercialization of novel medicines to treat chronic diseases with significant unmet need.

As of March 31, 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.

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 March 31, 2019, had an accumulated deficit of \$191.4 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.

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 three-month periods ended March 31, 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 March 31, 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 an Option, Collaboration and License Agreement (the Collaboration Agreement) and an Investment Agreement (the Investment Agreement) with Novartis Pharma AG (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, 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.

Potential future payments for variable consideration, such as clinical, regulatory or commercial milestones, will be recognized when it is probable that, if recorded, a significant reversal will not take place. Potential future royalty payments will be recorded as revenue when the associated sales occur.

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 March 31, 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):

	March	31,
	2019	2018
Warrants to purchase common stock	13	150
Common stock options issued and outstanding	6,759	5,528
Shares issuable upon conversion of convertible note payable		2,058
ESPP shares pending issuance	20	15
Total	6,792	7,751

# **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 March 31, 2019 and December 31, 2018 (in thousands):

		Quoted Prices in			
		Active Markets	Significant	Significant	
		for Identical	Other	Unobservable	
			Observable	Inputs	
	March 31,	Assets (L	evel	_	
	2019	1)	Inputs (Level 2)	(Level 3)	
Assets					
Cash	\$ 3,188	\$3,188	\$ —	\$ —	
Money market funds	8,999	8,999	_	_	
Corporate debt securities	21,646	_	21,646		
Total	\$ 33,833	\$12,187	\$ 21,646	\$ —	

Fair Value Measurements Using
December 31, Quoted Praignificant Significant
2018

Fair Value Measurements Using

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		Active Markets	Other	Unobservable	
		for	Observable	Inputs	
			Inputs (Level 2)	(Level 3)	
		Assets (Level 1)			
Assets		ŕ			
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):

	Maturity	Amortized	Unrealized	Unrealized	Estimated
	rracarrey	Timornzea	Cincuized	Cincuitzed	Fair
As of March 31, 2019	(in years)	Cost	Gains	Losses	Value
Corporate debt securities	1 or less	\$ 14,662	\$ 3	\$ -	- \$ 14,665
Total		\$ 14,662	\$ 3	\$ -	- \$ 14,665
					Estimated
	Maturity	Amortized	Unrealized	l Unrealized	
					Fair
As of December 31, 2018	(in years)	Cost	Gains	Losses	Value
Corporate debt securities	1 or less	\$ 29,144	\$ -	<b>-</b> \$ (17	) \$ 29,127
Total		\$ 29,144	\$ -	<b>-</b> \$ (17	\$ 29,127

# 5. Property and Equipment

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

	March 31, 2019	December 31, 2018
Furniture and fixtures	\$ 334	\$ 334
Equipment	219	208
Leasehold improvements	147	147
	700	689
Less accumulated depreciation and amortization	(555)	(535)
Total	\$ 145	\$ 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 March 31, 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 March 31, 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 three months ended March 31, 2019 (options in thousands):

		Weighted-
		Average
	Total	Exercise
	Options	Price
Balance at December 31, 2018	5,385	\$ 5.20
Granted	1,564	2.00
Exercised	_	_
Forfeited/cancelled/expired	(190)	6.17
Balance at March 31, 2019	6,759	\$ 4.43

# **Stock-Based Compensation**

The Company recorded stock-based compensation of \$0.9 million and \$1.0 million for the three months ended March 31, 2019 and 2018, respectively.

# Common Stock Reserved for Future Issuance

The following shares of common stock were reserved for future issuance at March 31, 2019 (in thousands):

Warrants to purchase common stock	13
Common stock options issued and outstanding	6,759
Common stock authorized for future option grants	470
Common stock authorized for the ESPP	495
Total	7,737

# 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.

Pursuant to the Collaboration Agreement, the Company is responsible for completing its two ongoing Phase 2b trials. 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.

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.

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

at
Reporting

Date

Balance at December 31, 2018 \$ 12,890

Additions to deferred revenue
Revenue recognized (7,024

Balance at March 31, 2019 \$ 9,726

The Company expects to recognize deferred revenue related to the Collaboration Agreement as follows (in thousands):

Within 1 year	\$8,150
1-2 years	1,576
Total deferred revenue	\$9,726

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		
	at Re	eportir	ng
	D	ate	
Balance at December 31, 2018	\$	310	
Costs recognized		(77	)
Balance at March 31, 2019	\$	233	

The Company expects to recognize deferred costs related to execution of the Collaboration Agreement as follows (in thousands):

Within 1 year	\$195
1-2 years	38
Total deferred costs	\$233

# 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 March 31, 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)	\$514
Current portion of lease liabilities	\$398
Lease liabilities, less current portion	229
Total lease liabilities	\$627

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 March 31, 2019 (in thousands):

Remaining in 2019	\$329
2020	351
Total lease payments	680
Present value adjustment	(53)
Total lease liabilities	\$627

For the three months ended March 31, 2019 and 2018, rent expense was as follows (in thousands):

	Three	
	Months	
	Ended	
	March 31,	
	2019	2018
Operating lease	\$95	\$ 95
Short-term leases	17	
Total	\$112	\$ 95

# 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.

# 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" 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 focused on the development and commercialization of novel medicines to treat chronic diseases with significant unmet need. We are 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. We are also developing CTS-2090, an orally active selective caspase inhibitor, for diseases involving inflammasome pathways.

We plan to continue clinical trials of emricasan in collaboration with Novartis Pharma AG, or Novartis, for patients with cirrhosis due to nonalcoholic steatohepatitis, or NASH. Our current clinical program for emricasan includes the following randomized, double-blind, placebo-controlled Phase 2b clinical trials:

Phase 2b ENCORE-LF (Liver Function) Clinical Trial: In May 2017, we initiated a clinical trial to evaluate emricasan in approximately 210 patients with decompensated NASH cirrhosis. Top-line results, triggered by reaching a prespecified number of events, are expected in mid-2019.

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Phase 2b ENCORE-PH (Portal Hypertension) Clinical Trial: In November 2016, we initiated a clinical trial to evaluate the effect of emricasan in approximately 240 compensated or early decompensated NASH cirrhosis patients with severe portal hypertension. In December 2018, we announced that top-line results from this trial did not meet the primary endpoint. Results from the six-month extension stage of the trial are expected in mid-2019. In March 2019, we announced top-line results from the Phase 2b ENCORE-NF (NASH Fibrosis) clinical trial of emricasan, which did not meet the primary endpoint. In addition, we initiated a non-treatment observational study in February 2018 pursuant to which subjects from the two trials above and the previously completed Phase 2b ENCORE-NF clinical trial and the Phase 2b clinical trial in post-orthotopic liver transplant, or POLT, patients with reestablished liver fibrosis as a result of recurrent hepatitis C virus, or HCV, infection who have successfully achieved a sustained viral response, or SVR, following HCV antiviral therapy, or POLT-HCV-SVR trial, will be followed for up to three years.

In May 2017, Novartis exercised its option under the Option, Collaboration and License Agreement, or the Collaboration Agreement, we entered into with Novartis in December 2016. Pursuant to such exercise, 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. The license became effective upon our receipt of a \$7.0 million option exercise payment in July 2017.

Pursuant to the Collaboration Agreement, we are responsible for completing the three ENCORE trials and the POLT-HCV-SVR trial described above. 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 described above, 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. A joint steering committee comprised of representatives from our company and Novartis oversees the collaboration, development and commercialization of emricasan products.

Under the Collaboration Agreement, Novartis paid us an upfront payment of \$50.0 million and the option exercise payment of \$7.0 million. In addition, we are eligible to receive up to an aggregate of \$650.0 million in milestone payments, as well as royalties.

We recently announced the selection of our first internally developed product candidate, CTS-2090, based on its preclinical profile, including high selectivity for caspase 1, and drug-like properties. CTS-2090 is currently in preclinical development and studies to enable the filing of an investigational new drug application, or IND, with an initial clinical trial planned to begin by the first half of 2020. We plan to pursue rare autoinflammatory diseases as initial clinical targets for CTS-2090. We also may expand our development pipeline by internal development of additional preclinical product candidates leveraging our caspase inhibition expertise or in-licensing or acquiring preclinical or clinical-stage product candidates consistent with our product development and regulatory expertise.

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 \$4.7 million for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of \$191.4 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 for the foreseeable future as we continue the clinical development of emricasan and seek regulatory approval for and, if approved, pursue co-commercialization of emricasan. 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 March 31, 2019, we had cash, cash equivalents and marketable securities of \$33.8 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, including the development of internally developed and/or in-licensed product candidates other than emricasan or the co-commercialization of emricasan with Novartis. 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.

We currently 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 in the development of emricasan in a timely manner and/or obtain regulatory approval for this product candidate, or to successfully develop other product candidates, our ability to generate future revenues would be materially adversely affected.

# 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 \$155.5 million of research and development expenses in the development of emricasan through March 31, 2019. Our business model is currently 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. The development of emricasan and CTS-2090 are dependent upon our continuing to conduct research and a significant amount of preclinical and clinical development. 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.

At this time, due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the costs we will incur in the continued development of emricasan and CTS-2090. 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.

We are currently focused on advancing emricasan and CTS-2090 in multiple indications, and our future research and development expenses will depend on their preclinical and clinical success. In addition, we cannot forecast with any degree of certainty to what extent Novartis will develop and commercialize emricasan under the Collaboration Agreement.

Research and development expenditures will continue to be significant as we continue clinical development of emricasan and preclinical and clinical development of CTS-2090 over at least the next several years. We expect to incur significant development costs as we conduct our ongoing Phase 2b trials of emricasan and preclinical studies of CTS-2090, as well as development of other potential product candidates.

We do not expect emricasan or CTS-2090 to be commercially available, if at all, for at least the next several years.

#### 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.

If we exercise our option to co-commercialize emricasan pursuant to the Collaboration Agreement, we may incur expenses associated with activities related to commercializing emricasan. Some expenses may be incurred prior to receiving regulatory approval of emricasan. We do not expect to receive any such regulatory approval for at least the next several years.

#### 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 three months ended March 31, 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 March 31, 2019 and 2018

#### **Total Revenues**

Total revenues were \$7.0 million for the three months ended March 31, 2019, as compared to \$9.7 million for the same period in 2018. The decrease of \$2.7 million was primarily due to lower emricasan-related research and development expenses resulting in corresponding lower revenues related to the Collaboration Agreement.

Under the relevant revenue recognition guidance, we recognize collaboration revenue in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. We periodically review and update the estimated collaboration expenses, when appropriate, which adjusts the percentage of revenue that is recognized for the period. Such changes could materially impact the amount of revenue recorded in the period.

#### Research and Development Expenses

Research and development expenses were \$9.4 million for the three months ended March 31, 2019, as compared to \$12.1 million for the same period in 2018. The decrease of \$2.7 million was primarily due to lower spending related to our ENCORE-PH clinical trial and manufacturing activities, partially offset by higher spending related to our ENCORE-LF clinical trial.

#### General and Administrative Expenses

General and administrative expenses were \$2.6 million for the three months ended March 31, 2019, as compared to \$2.7 million for the same period in 2018.

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

## Interest Income

Interest income was \$200,000 for the three months ended March 31, 2019, as compared to \$233,000 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 March 31, 2019, as compared to \$185,000 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 three months ended March 31, 2019, as compared to other expense of \$9,000 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 March 31, 2019, we had an accumulated deficit of \$191.4 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of emricasan and CTS-2090.

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.

At March 31, 2019, we had cash, cash equivalents and marketable securities of \$33.8 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. 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. 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):

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	\$(6,964)	\$(8,154)
Net cash provided by investing activities	14,567	8,653
Net cash provided by financing activities		37
Net increase in cash and cash equivalents	\$7,603	\$536

Net cash used in operating activities was \$7.0 million and \$8.2 million for the three months ended March 31, 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 \$14.6 million and \$8.7 million for the three months ended March 31, 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 \$0 for the three months ended March 31, 2019. Net cash provided by financing activities was \$37,000 for the three months ended March 31, 2018, which consisted primarily of proceeds from the exercise of stock options.

## **Contractual Obligations and Commitments**

As of March 31, 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 March 31, 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 factor below.

If we fail to meet all applicable Nasdaq Global Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on the Nasdaq Global Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum closing bid price per share of \$1.00 and continued business operations so that we are not characterized as a "public shell company." As of the date hereof, the closing bid price of our common stock is below \$1.00 per share. If we were to fail to meet the minimum closing bid price requirement of \$1.00 for 30 consecutive business days, we could become subject to delisting. Although Nasdaq may provide us with a compliance period in which to regain compliance with the minimum closing bid price requirement, we cannot assure you that we would be able to regain compliance within the period provided by Nasdaq. In order to regain compliance with such requirement, the closing bid price of our common stock would need to meet or exceed \$1.00 per share for at least 10 consecutive business days during the compliance period. If we were not able to regain compliance within the allotted compliance period for this requirement or any other applicable listing standard, including any extensions that may be granted by Nasdaq, our shares of common stock would be subject to delisting. 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.

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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.
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## **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

- (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.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

(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: May 3, 2019 /s/ Steven J. Mento, Ph.D.
Steven J. Mento, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: May 3, 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)