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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

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(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018**

**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**  
**(State or Other Jurisdiction of**  
**Incorporation or Organization)**

**16745 W. Bernardo Dr., Suite 200**  
**San Diego, CA**  
**(Address of Principal Executive Offices)**

**20-3183915**  
**(I.R.S. Employer**  
**Identification No.)**

**92127**  
**(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.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

As of October 25, 2018, the registrant had 30,261,547 shares of common stock (\$0.0001 par value) outstanding.

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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)

	September 30, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 13,308	\$ 16,079
Marketable securities	36,312	58,774
Collaboration receivables	4,109	3,367
Prepaid and other current assets	3,170	1,004
Total current assets	56,899	79,224
Property and equipment, net	124	179
Other assets	1,119	2,538
Total assets	<u>\$ 58,142</u>	<u>\$ 81,941</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,123	\$ 11,962
Accrued compensation	1,976	2,008
Current portion of deferred revenue	12,661	14,172
Total current liabilities	23,760	28,142
Deferred revenue, less current portion	3,962	12,519
Convertible note payable	13,718	13,158
Deferred rent	84	126
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; 30,262 shares issued and outstanding at September 30, 2018; 30,035 shares issued and outstanding at December 31, 2017	3	3
Additional paid-in capital	199,350	196,077
Accumulated other comprehensive loss	(12)	(77)
Accumulated deficit	(182,723)	(168,007)
Total stockholders' equity	16,618	27,996
Total liabilities and stockholders' equity	<u>\$ 58,142</u>	<u>\$ 81,941</u>

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Revenues:</b>				
Collaboration revenue	\$ 7,666	\$ 9,566	\$ 26,177	\$ 26,572
<b>Total revenues</b>	<b>7,666</b>	<b>9,566</b>	<b>26,177</b>	<b>26,572</b>
<b>Operating expenses:</b>				
Research and development	9,664	11,165	32,482	32,309
General and administrative	2,660	2,449	7,967	7,406
<b>Total operating expenses</b>	<b>12,324</b>	<b>13,614</b>	<b>40,449</b>	<b>39,715</b>
Loss from operations	(4,658)	(4,048)	(14,272)	(13,143)
<b>Other income (expense):</b>				
Interest income	253	259	730	648
Interest expense	(189)	(189)	(561)	(473)
Other income (expense)	5	(22)	(1)	(72)
<b>Total other income</b>	<b>69</b>	<b>48</b>	<b>168</b>	<b>103</b>
Net loss	(4,589)	(4,000)	(14,104)	(13,040)
<b>Other comprehensive income (loss):</b>				
Net unrealized gains (losses) on marketable securities	29	(1)	65	(17)
<b>Comprehensive loss</b>	<b>\$ (4,560)</b>	<b>\$ (4,001)</b>	<b>\$ (14,039)</b>	<b>\$ (13,057)</b>
Net loss per share, basic and diluted	\$ (0.15)	\$ (0.13)	\$ (0.47)	\$ (0.46)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	30,190	30,004	30,118	28,104

*See accompanying notes to condensed financial statements.*

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

	<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
<b>Operating activities</b>		
Net loss	\$ (14,104)	\$ (13,040)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	72	81
Stock-based compensation expense	2,860	3,049
Amortization of premiums and discounts on marketable securities, net	(230)	(13)
Accrued interest included in convertible note payable	560	469
Changes in operating assets and liabilities:		
Collaboration receivables	(742)	2,500
Prepaid and other current assets	305	(458)
Other assets	(246)	(872)
Accounts payable and accrued expenses	(2,863)	5,617
Accrued compensation	(32)	(541)
Deferred revenue	(11,367)	(19,572)
Deferred rent	(32)	(23)
Net cash used in operating activities	<u>(25,819)</u>	<u>(22,803)</u>
<b>Investing activities</b>		
Maturities of marketable securities	56,435	57,257
Purchase of marketable securities	(33,678)	(109,152)
Capital expenditures	(15)	(25)
Net cash provided by (used in) investing activities	<u>22,742</u>	<u>(51,920)</u>
<b>Financing activities</b>		
Proceeds from issuance of convertible note payable, net	—	12,500
Principal payment on promissory note	—	(1,000)
Proceeds from issuance of common stock, net	—	30,610
Repurchase of common stock	—	(11,203)
Deferred financing costs	(107)	—
Proceeds from stock issuances related to exercise of stock options and employee stock purchase plan	413	93
Net cash provided by financing activities	<u>306</u>	<u>31,000</u>
Net decrease in cash and cash equivalents	(2,771)	(43,723)
Cash and cash equivalents at beginning of period	16,079	58,083
Cash and cash equivalents at end of period	<u>\$ 13,308</u>	<u>\$ 14,360</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ —</u>	<u>\$ 5</u>

See accompanying notes to condensed financial statements.

**Conatus Pharmaceuticals Inc.**  
**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 liver disease.

As of September 30, 2018, 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 September 30, 2018, had an accumulated deficit of \$182.7 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, 2017 included in the Company's annual report on Form 10-K filed with the SEC on March 8, 2018.

**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 nine-month periods ended September 30, 2018 and 2017.

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 prepaid and other current assets, 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 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 September 30, 2018.

#### ***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 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 of the Collaboration Agreement consists of the upfront payment, option exercise fee, deemed revenue from the premium paid by Novartis under the Investment Agreement and reimbursable research and development costs, net of certain expenses directly related to execution of the agreement.

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, 2017, 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 September 30, 2018. 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, 2017, 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):

	September 30,	
	2018	2017
Warrants to purchase common stock	13	150
Common stock options issued and outstanding	5,370	4,911
Shares issuable upon conversion of convertible note payable	2,658	2,297
ESPP shares pending issuance	18	7
Total	8,059	7,365

### Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This guidance requires that an entity recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. For public companies, ASU No. 2014-09 is effective for annual reporting periods beginning after December 15, 2017 and interim periods within that reporting period. The Company adopted this guidance effective January 1, 2018, as required, utilizing the modified retrospective method. The change in accounting standard primarily affects the Company's recognition of collaboration revenue under the Collaboration Agreement. Under prior guidance, the Company recognized collaboration revenue under the Collaboration Agreement over the estimated time-based performance period for license-related payments and when costs were incurred for reimbursable costs. Under current guidance, the Company recognizes collaboration revenue and some related expenses in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. Another feature of the new standard is that recognition of variable consideration such as milestone payments may be accelerated. Under the modified retrospective adoption method, the Company recognized the retrospective cumulative effect of applying the standard for contracts that have remaining obligations as of the effective date, namely the Collaboration Agreement, to the opening balance of retained earnings (accumulated deficit) and will apply the standard to all new contracts initiated on or after the effective date. Adoption of this guidance resulted in a net increase in the accumulated deficit of \$0.6 million. Additionally, adoption of this guidance had no impact on the Company's income tax expense, and the Company expects the impact on its tax provision to be immaterial due to the full valuation allowance. Under prior guidance, revenue recognized under the Collaboration Agreement would have been \$24.1 million for the nine months ended September 30, 2018, which is \$2.1 million lower than the amount recognized under current guidance.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. This guidance requires organizations that lease assets with lease terms of more than 12 months to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. The ASU also requires disclosures to give financial statement users information on the amount, timing and uncertainty of cash flows arising from leases, including qualitative and quantitative information. For public companies, ASU No. 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the impact of the pending adoption of ASU No. 2016-02 on its financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718)*. This guidance simplifies the accounting for nonemployee stock-based compensation and largely aligns such compensation with the accounting requirements for employee stock-based awards. For public companies, ASU No. 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The Company early adopted this guidance effective June 30, 2018. The adoption of this guidance had an immaterial impact on the Company's financial statements and related disclosures.

### 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 equivalents and marketable securities, measured at fair value as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 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)
<b>Assets</b>				
Money market funds	\$ 8,658	\$ 8,658	\$ —	\$ —
U.S. agency securities	998	—	998	—
Corporate debt securities	38,806	—	38,806	—
<b>Total</b>	<b>\$ 48,462</b>	<b>\$ 8,658</b>	<b>\$ 39,804</b>	<b>\$ —</b>

	December 31, 2017	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)
<b>Assets</b>				
Money market funds	\$ 12,218	\$ 12,218	\$ —	\$ —
Corporate debt securities	61,774	—	61,774	—
<b>Total</b>	<b>\$ 73,992</b>	<b>\$ 12,218</b>	<b>\$ 61,774</b>	<b>\$ —</b>

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 September 30, 2018	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	\$ 36,324	\$ 2	\$ (14)	\$ 36,312
Total		\$ 36,324	\$ 2	\$ (14)	\$ 36,312

  

As of December 31, 2017	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	\$ 58,851	\$ —	\$ (77)	\$ 58,774
Total		\$ 58,851	\$ —	\$ (77)	\$ 58,774

#### 5. Property and Equipment

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

	September 30, 2018	December 31, 2017
Furniture and fixtures	\$ 334	\$ 334
Equipment	165	143
Leasehold improvements	147	152
	646	629
Less accumulated depreciation and amortization	(522)	(450)
Total	\$ 124	\$ 179

#### 6. Note Payable

In July 2010, the Company issued to Pfizer Inc. (Pfizer) a \$1.0 million promissory note (the Pfizer Note). The Pfizer Note bore interest at a rate of 7% per annum and was scheduled to mature on July 29, 2020. Interest was payable on a quarterly basis. On January 24, 2017, the Company voluntarily prepaid the entire balance of the outstanding principal and accrued and unpaid interest of the Pfizer Note in the amount of \$1,004,861.

Prior to the prepayment of the Pfizer Note, the Company recorded the Pfizer Note on the balance sheet at face value. Based on borrowing rates available to the Company for loans with similar terms, the Company believed that the fair value of the Pfizer Note approximated its carrying value. The fair value measurement was categorized within Level 3 of the fair value hierarchy.

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 bears interest on the unpaid principal balance at a rate of 6% per annum and has a scheduled maturity date of December 31, 2019. The Company may prepay or convert all or part of the Novartis Note into shares of the Company's common stock, at its option, until December 31, 2019. Novartis has the option to convert all or part of the Novartis Note into shares of the Company's common stock upon a change in control of the Company or termination of the Collaboration Agreement by Novartis pursuant to certain provisions. If converted, the principal and accrued interest under the Novartis Note will convert 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. In the event the aggregate number of shares of common stock issued upon the conversion would exceed the lesser of 19.0% of the Company's outstanding shares on a fully-diluted basis (i) at the inception of the Investment Agreement or (ii) on the conversion date, then only the lesser amount shall convert into

shares of common stock and Novartis shall be repaid in cash for any remaining principal and unpaid interest after such conversion. Upon the occurrence of certain events of default, the Novartis Note requires the Company to repay the principal balance of the Novartis Note and any unpaid accrued interest. 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. The convertible note payable, along with the related accrued interest, totaled \$13.7 million as of September 30, 2018.

The Company elected to account for the Novartis Note under the fair value option. At September 30, 2018, the Company concluded that the fair value of the Novartis Note remained at \$13.7 million due to its conversion features. The fair value measurement is 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 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 September 30, 2018, 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 September 30, 2018, no shares were issued pursuant to the Sales Agreement.

### *Warrants*

In 2013, the Company issued warrants exercisable for 1,124,026 shares of Series B preferred stock, at an exercise price of \$0.90 per share, to certain existing investors in conjunction with a private placement (the 2013 Warrants) and 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 (IPO), the 2013 Warrants and the Lender Warrants became exercisable for 136,236 and 13,468 shares of common stock, respectively, at an exercise price of \$7.43 per share. The 2013 Warrants expired on May 30, 2018, and 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 nine months ended September 30, 2018 (options in thousands):

	<b>Total Options</b>	<b>Weighted- Average Exercise Price</b>
Balance at December 31, 2017	4,826	\$ 5.05
Granted	926	5.13
Exercised	(211)	1.71
Forfeited/cancelled/expired	(171)	4.82
Balance at September 30, 2018	<u>5,370</u>	<u>\$ 5.20</u>

### *Stock-Based Compensation*

The Company recorded stock-based compensation of \$0.9 million and \$1.0 million for the three months ended September 30, 2018 and 2017, respectively, and \$2.9 million and \$3.0 million for the nine months ended September 30, 2018 and 2017, respectively.

### **Common Stock Reserved for Future Issuance**

The following shares of common stock were reserved for future issuance at September 30, 2018 (in thousands):

Warrants to purchase common stock	13
Common stock options issued and outstanding	5,370
Common stock authorized for future option grants	859
Common stock authorized for the ESPP	516
Shares issuable upon conversion of convertible note payable	2,658
Total	<u>9,416</u>

### **8. Collaboration and License Agreements**

In December 2016, the Company entered into the Collaboration Agreement with Novartis, 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 three 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 with Novartis whereby the Company is able to borrow up to \$15.0 million at a rate of 6% per annum, under one or two notes, which will mature on December 31, 2019. The Company may elect at its sole discretion to convert all or part of the outstanding principal and accrued interest into fully paid shares of common stock, at 120% of the 20-day trailing average closing price per share of the common stock immediately prior to the conversion date. Novartis has the option to convert all or part of the note(s) into shares of the Company's common stock upon a change in control of the Company or termination of the Collaboration Agreement by Novartis pursuant to certain provisions. In the event the conversion of the notes would exceed the lesser of 19.0% of the Company's outstanding shares on a fully-diluted basis (i) at the inception of the Investment Agreement or (ii) on the conversion date, then only the lesser amount shall convert into shares of common stock and Novartis shall be repaid in cash for any remaining principal and unpaid interest after such conversion. On February 15, 2017, the Company issued the Novartis Note in the principal amount of \$15.0 million pursuant to the Investment Agreement.

## 9. Commitments

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. Future minimum payments under this noncancelable operating lease total \$0.9 million at September 30, 2018.

Rent expense was \$0.1 million for each of the three-month periods ended September 30, 2018 and 2017 and \$0.3 million for each of the nine-month periods ended September 30, 2018 and 2017.

In July 2010, the Company entered into a stock purchase agreement with 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, 2017 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, 2018.

### 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 focused on the development and commercialization of novel medicines to treat liver disease. We are developing emricasan, a first-in-class, orally active pan-caspase protease 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 believe that by reducing the activity of these enzymes, caspase inhibitors have the potential to interrupt the progression of a variety of diseases.

We plan to continue advancing toward registration of emricasan in collaboration with Novartis Pharma AG, or Novartis, for patients with fibrosis or 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-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. The primary endpoint is the mean change in hepatic venous pressure gradient for each of three treatment groups compared with placebo at week 24. Top-line results are expected in the fourth quarter of 2018. In addition, this trial has a 24-week treatment extension that is intended to further evaluate clinical outcomes.
- *Phase 2b ENCORE-NF (NASH Fibrosis) Clinical Trial:* In January 2016, we initiated a clinical trial to evaluate emricasan in approximately 330 patients with liver fibrosis resulting from NASH. The primary endpoint is a one point or greater improvement in NASH Clinical Research Network, or CRN, fibrosis score compared with placebo at week 72, with no worsening of steatohepatitis. This trial enrolled patients with baseline NASH CRN fibrosis scores of F1 (up to 20% of enrolled patients), F2 and F3. The primary endpoint will be evaluated and can be achieved in either of two prospectively defined patient populations – the F1/F2/F3 population or the F2/F3 population – either of which may be used in a future Phase 3 clinical trial. We believe the ENCORE-NF analysis plan as described has the potential to facilitate discussions with regulatory authorities regarding its use as a trial to support regulatory approval. Top-line results are expected in the first half of 2019.
- *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. The primary endpoint is event-free survival, with an event-driven stopping point. All subjects will be treated for a minimum of 48 weeks. Top-line results are expected in mid-2019.

In February 2018, we initiated a non-treatment observational study pursuant to which subjects from the three trials above and the completed Phase 2b POLT-HCV-SVR trial will be followed for an up to three-year safety follow-up.

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 described above. We share the costs of the ENCORE trials equally with Novartis. In addition, until the completion of the ENCORE trials, we will equally share the costs of the non-treatment observational study. After the completion of the ENCORE 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 ENCORE 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 also plan to expand our development pipeline by internally developing new preclinical product candidates leveraging our expertise with caspase inhibition and/or by in-licensing or acquiring preclinical or clinical product candidates consistent with our product development and regulatory expertise. We will continue to evaluate the potential of IDN-7314, a pan-caspase inhibitor designed for the treatment of primary sclerosing cholangitis, as a product candidate as a component of our pipeline expansion plans. In addition to liver disease, we may pursue the development of product candidates in other disease areas.

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 \$17.4 million and \$29.7 million for the years ended December 31, 2017 and 2016, respectively, and \$14.1 million for the nine months ended September 30, 2018. As of September 30, 2018, we had an accumulated deficit of \$182.7 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 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 September 30, 2018, we had cash, cash equivalents and marketable securities of \$49.6 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.



## **JOBS Act**

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an “emerging growth company,” we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an “emerging growth company” we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor’s attestation report on our system of internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering, or IPO, or until we no longer meet the requirements of being an “emerging growth company,” whichever is earlier.

## **Financial Overview**

### ***Revenues***

Our revenues to date have been generated primarily from the Collaboration Agreement with Novartis. 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 \$139.2 million of research and development expenses in the development of emricasan through September 30, 2018. Our business model is currently focused on the development of emricasan in various liver diseases in collaboration with Novartis and is dependent upon our continuing to conduct research and a significant amount of 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. 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 in multiple indications, and our future research and development expenses will depend on its 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 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 develop product candidates other than emricasan.

We do not expect emricasan 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 coupon interest on our \$1.0 million promissory note payable to Pfizer Inc., or the Pfizer Note, which was voluntarily prepaid in January 2017.

#### ***Other Income (Expense)***

Other income (expense) includes non-operating transactions such as those caused by currency fluctuations between transaction dates and settlement dates and the conversion of account balances held in foreign currencies to U.S. dollars.

## **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 nine months ended September 30, 2018 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, 2017 filed with the SEC on March 8, 2018, other than the critical accounting policy below, which relates to the adoption of a new revenue recognition standard.

### ***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. We perform 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, we satisfy a performance obligation.

At contract inception, we identify 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, we 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. We evaluate 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 our intellectual property is determined to be distinct from the other performance obligations identified in a contract, we recognize 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, we utilize 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. We evaluate the measure of progress at each reporting period and, if necessary, adjust 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, we evaluate 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 our 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, we re-evaluate the probability of achievement of milestones that are within our or a collaboration partner's control, such as operational developmental milestones and any related constraint, and, if necessary, adjust our 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 our 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, we 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, we have not recognized any royalty revenue from collaborative arrangements.

In December 2016, we entered into the Collaboration Agreement and an Investment Agreement, the Investment Agreement, with Novartis. We 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 we are uniquely able to perform.

We 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. We periodically review and update the estimated collaboration expenses, when appropriate, which adjusts the percentage of revenue that is recognized for the period. While such changes to our estimates have no impact on our reported cash flows, the amount of revenue recorded in the period could be materially impacted. The transaction price of the Collaboration Agreement consists of the upfront payment, option exercise fee, deemed revenue from the premium paid by Novartis under the Investment Agreement and reimbursable research and development costs, net of certain expenses directly related to execution of the agreement.

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.

## **Results of Operations**

### ***Comparison of the Three Months Ended September 30, 2018 and 2017***

#### *Total Revenues*

Total revenues were \$7.7 million for the three months ended September 30, 2018, as compared to \$9.6 million for the same period in 2017. The decrease of \$1.9 million was primarily due to lower emricasan-related research and development expenses resulting in corresponding lower revenues related to the Collaboration Agreement, partially offset by the effect of our adoption of the new revenue recognition standard described above.

Under prior guidance, we recognized collaboration revenue under the Collaboration Agreement over the estimated time-based performance period for license-related payments and when costs were incurred for reimbursable costs. Under the new revenue recognition standard, which we adopted on January 1, 2018, we recognize collaboration revenue and some related expenses 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 \$9.7 million for the three months ended September 30, 2018, as compared to \$11.2 million for the same period in 2017. The decrease of \$1.5 million was primarily due to lower spending related to our ENCORE-NF and ENCORE-PH clinical trials and manufacturing activities, partially offset by higher spending related to our ENCORE-LF clinical trial.

#### *General and Administrative Expenses*

General and administrative expenses were \$2.7 million for the three months ended September 30, 2018, as compared to \$2.4 million for the same period in 2017. The increase of \$0.3 million was primarily due to higher personnel costs.

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

#### *Interest Income*

Interest income was \$253,000 for the three months ended September 30, 2018, as compared to \$259,000 for the same period in 2017. 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 \$189,000 for each of the three-month periods ended September 30, 2018 and 2017 and consisted of interest related to the Novartis Note, which was issued in February 2017.

### *Other Income (Expense)*

Other income was \$5,000 for the three months ended September 30, 2018, as compared to other expense of \$22,000 for the same period in 2017. Other income (expense) represents non-operating transactions such as those caused by currency fluctuations between transaction dates and settlement dates.

### ***Comparison of the Nine Months Ended September 30, 2018 and 2017***

#### *Total Revenues*

Total revenues were \$26.2 million for the nine months ended September 30, 2018, as compared to \$26.6 million for the same period in 2017. The decrease of \$0.4 million was primarily due to lower emricasan-related research and development expenses resulting in corresponding lower revenues related to the Collaboration Agreement, partially offset by the effect of our adoption of the new revenue recognition standard described above.

#### *Research and Development Expenses*

Research and development expenses were \$32.5 million for the nine months ended September 30, 2018, as compared to \$32.3 million for the same period in 2017. The increase of \$0.2 million was primarily due to higher spending related to our ENCORE-LF and ENCORE-PH clinical trials and new product candidate development, partially offset by lower spending related to our ENCORE-NF clinical trial and manufacturing activities.

#### *General and Administrative Expenses*

General and administrative expenses were \$8.0 million for the nine months ended September 30, 2018, as compared to \$7.4 million for the same period in 2017. The increase of \$0.6 million was primarily due to higher personnel costs.

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

#### *Interest Income*

Interest income was \$730,000 for the nine months ended September 30, 2018, as compared to \$648,000 for the same period in 2017. 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 \$561,000 for the nine months ended September 30, 2018, as compared to \$473,000 for the same period in 2017. The increase was primarily due to higher interest expense related to the Novartis Note, which was issued in February 2017.

#### *Other Income (Expense)*

Other expense was \$1,000 for the nine months ended September 30, 2018, as compared to \$72,000 for the same period in 2017. 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 with Novartis. As of September 30, 2018, we had an accumulated deficit of \$182.7 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.

Prior to our 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 with Novartis 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 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. The maturity date of the Novartis Note is December 31, 2019. The Novartis Note bears interest on the unpaid principal balance at a rate of 6% per annum. We may prepay or convert the Novartis Note into shares of our common stock, at our option, until December 31, 2019. Novartis may convert the Novartis Note into shares of our common stock upon a change of control of our company or termination of the Collaboration Agreement by Novartis pursuant to certain provisions. If converted, the principal and accrued interest under the Novartis Note will convert 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. Upon the occurrence of certain events of default, the Novartis Note requires us to repay the principal balance and any unpaid accrued interest.

On August 2, 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 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 September 30, 2018, we had cash, cash equivalents and marketable securities of \$49.6 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):

	<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
Net cash used in operating activities	\$ (25,819)	\$ (22,803)
Net cash provided by (used in) investing activities	22,742	(51,920)
Net cash provided by financing activities	306	31,000
Net decrease in cash and cash equivalents	<u>\$ (2,771)</u>	<u>\$ (43,723)</u>

Net cash used in operating activities was \$25.8 million and \$22.8 million for the nine months ended September 30, 2018 and 2017, respectively. The primary use of cash was to fund our operations related to the development of emricasan.

Net cash provided by investing activities was \$22.7 million for the nine months ended September 30, 2018, which consisted primarily of proceeds from maturities of marketable securities, partially offset by cash used to purchase marketable securities. Net cash used in investing activities was \$51.9 million for the nine months ended September 30, 2017, which consisted primarily of cash used to purchase marketable securities, partially offset by proceeds from maturities of marketable securities.

Net cash provided by financing activities was \$0.3 million for the nine months ended September 30, 2018, which consisted primarily of proceeds from the exercise of stock options. Net cash provided by financing activities was \$31.0 million for the nine months ended September 30, 2017, which consisted primarily of net proceeds from our public offering in May 2017 and proceeds from the issuance of the Novartis Note in February 2017, partially offset by the repurchase of shares from Advent in May 2017 and the voluntary prepayment of the Pfizer Note in January 2017.

#### **Contractual Obligations and Commitments**

As of September 30, 2018, 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, 2017 filed with the SEC on March 8, 2018.

#### **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**

As of September 30, 2018, there have been no material changes in our market risk from that described in “Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in our annual report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission on March 8, 2018.

#### **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 September 30, 2018, 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, 2017 filed with the Securities and Exchange Commission on March 8, 2018, other than the risk factor below.

***If Novartis Pharma AG, or Novartis, terminates the Option, Collaboration and License Agreement, or the Collaboration Agreement, and we fail to obtain additional financing, we may be unable to complete the development and commercialization of emricasan.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of emricasan, including our ongoing clinical trials. We believe the payments under the Collaboration Agreement and our existing capital resources will fund our share of the development costs for emricasan. If Novartis terminates the Collaboration Agreement, we will require significant additional amounts in order to continue clinical development and, if approved, launch and commercialize emricasan. To date, our operations have been primarily funded through the proceeds from the issuance of our common and preferred stock, including the proceeds from our initial public offering, or IPO, completed in July 2013 and follow-on public offerings completed in April 2015 and May 2017, as well as sales of common stock under our prior At Market Issuance Sales Agreement with MLV & Co. LLC.

In August 2018, we entered into an At Market Issuance Sales Agreement, or the 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 through Stifel, as sales agent. Sales of our common stock made pursuant to the 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 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 Sales Agreement will automatically terminate upon the sale of an aggregate of \$35.0 million of shares of our common stock pursuant to the Sales Agreement. In addition, the 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 Sales Agreement. There can be no assurance that Stifel will be successful in consummating sales under the Sales Agreement based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

We expect to fund our near-term operations primarily with the upfront payment of \$50.0 million that we received from Novartis in December 2016 pursuant to the Collaboration Agreement, proceeds from the issuance of a convertible promissory note in the principal amount of \$15.0 million, which we issued to Novartis in February 2017, the option exercise payment of \$7.0 million that we received from Novartis in July 2017 pursuant to the Collaboration Agreement, and potential sale of common stock under the Sales Agreement.

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. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We will require additional capital for the development and commercialization of product candidates other than emricasan.

We may seek to obtain additional financing in the future through the issuance of our common stock under the Sales Agreement or in public offerings, through other equity or debt financings or through collaborations or partnerships with other companies. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of emricasan or other research and development initiatives.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

**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
1.1(1)	<a href="#"><u>At Market Issuance Sales Agreement, dated August 2, 2018, between the Registrant and Stifel, Nicolaus &amp; Company, Incorporated</u></a>
3.1(2)	<a href="#"><u>Amended and Restated Certificate of Incorporation</u></a>
3.2(2)	<a href="#"><u>Amended and Restated Bylaws</u></a>
4.1(3)	<a href="#"><u>Specimen Common Stock Certificate</u></a>
4.2(4)	<a href="#"><u>First Amended and Restated Investor Rights Agreement, dated February 9, 2011</u></a>
4.3(4)	<a href="#"><u>Form of Warrant issued to investors in the Registrant's 2013 bridge financing</u></a>
4.4(3)	<a href="#"><u>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</u></a>
31.1	<a href="#"><u>Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended</u></a>
31.2	<a href="#"><u>Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended</u></a>
32.1*	<a href="#"><u>Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
32.2*	<a href="#"><u>Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
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

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- (1) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the SEC on August 2, 2018.
- (2) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 1, 2013.
- (3) 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.
- (4) 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: November 1, 2018

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

Date: November 1, 2018

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

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: November 1, 2018

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

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: November 1, 2018

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

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 September 30, 2018, 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: November 1, 2018

/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.

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 September 30, 2018, 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: November 1, 2018

/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.



