

# CONATUS PHARMACEUTICALS INC.

## FORM 10-Q (Quarterly Report)

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

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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 November 1, 2016, the registrant had 26,067,154 shares of common stock (\$0.0001 par value) outstanding.

CONATUS PHARMACEUTICALS INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Conatus Pharmaceuticals Inc.

Condensed Balance Sheets  
(Unaudited)

	September 30, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,313,617	\$ 13,876,090
Marketable securities	16,750,005	22,632,019
Prepaid and other current assets	1,137,384	1,982,031
Total current assets	32,201,006	38,490,140
Property and equipment, net	285,023	344,734
Other assets	876,130	892,394
Total assets	<u>\$ 33,362,159</u>	<u>\$ 39,727,268</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,354,507	\$ 2,545,894
Accrued compensation	1,609,668	1,436,804
Total current liabilities	3,964,175	3,982,698
Note payable	1,000,000	1,000,000
Deferred rent	181,637	204,224
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 25,179,655 shares issued and 25,173,339 shares outstanding, excluding 6,316 shares subject to repurchase, at September 30, 2016; 19,877,857 shares issued and 19,845,611 shares outstanding, excluding 32,246 shares subject to repurchase, at December 31, 2015	2,517	1,984
Additional paid-in capital	169,713,802	155,441,280
Accumulated other comprehensive income (loss)	8,978	(3,907)
Accumulated deficit	(141,508,950)	(120,899,011)
Total stockholders' equity	28,216,347	34,540,346
Total liabilities and stockholders' equity	<u>\$ 33,362,159</u>	<u>\$ 39,727,268</u>

See accompanying notes to condensed financial statements.

Conatus Pharmaceuticals Inc.

Condensed Statements of Operations and Comprehensive Loss  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 4,825,421	\$ 4,103,257	\$ 13,770,371	\$ 12,056,997
General and administrative	2,069,447	1,958,078	6,883,708	6,033,739
Total operating expenses	6,894,868	6,061,335	20,654,079	18,090,736
Other income (expense):				
Interest income	33,640	19,680	94,995	49,076
Interest expense	(17,500)	(17,500)	(52,500)	(52,500)
Other income (expense)	11,818	(8,391)	1,645	(10,304)
Total other income (expense)	27,958	(6,211)	44,140	(13,728)
Net loss	(6,866,910)	(6,067,546)	(20,609,939)	(18,104,464)
Other comprehensive income (loss):				
Net unrealized (losses) gains on marketable securities	(9,999)	10,702	12,885	14,108
Comprehensive loss	\$ (6,876,909)	\$ (6,056,844)	\$ (20,597,054)	\$ (18,090,356)
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.31)	\$ (0.96)	\$ (0.99)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	22,410,702	19,668,287	21,527,993	18,209,871

See accompanying notes to condensed financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Operating activities</b>		
Net loss	\$ (20,609,939)	\$ (18,104,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	79,877	50,738
Stock-based compensation expense	2,456,196	2,574,379
Amortization of premium on marketable securities	6,323	283,523
Changes in operating assets and liabilities:		
Prepaid and other current assets	844,647	(82,815)
Accounts payable and accrued expenses	(97,396)	(754,244)
Accrued compensation	175,197	243,699
Deferred rent	(13,313)	91,924
Net cash used in operating activities	(17,158,408)	(15,697,260)
<b>Investing activities</b>		
Maturities of marketable securities	30,847,000	44,724,000
Purchase of marketable securities	(24,958,424)	(46,737,972)
Capital expenditures	(107,165)	(4,695)
Net cash provided by (used in) investing activities	5,781,411	(2,018,667)
<b>Financing activities</b>		
Proceeds from issuance of common stock, net of offering costs	11,781,626	22,313,252
Proceeds from stock issuances under employee stock purchase plan and exercise of stock options	32,898	48,941
Net cash provided by financing activities	11,814,524	22,362,193
Net increase in cash and cash equivalents	437,527	4,646,266
Cash and cash equivalents at beginning of period	13,876,090	9,912,674
Cash and cash equivalents at end of period	\$ 14,313,617	\$ 14,558,940
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 52,500	\$ 52,500

*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, 2016, the Company has devoted substantially all of its efforts to product development and has not realized 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, 2016, had an accumulated deficit of \$141.5 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, 2015 included in the Company's annual report on Form 10-K filed with the SEC on March 11, 2016.

**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 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, 2016 and 2015.

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. 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, 2016.

#### ***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, 2015, 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, 2016. 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, 2015, 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, which include warrants to purchase common stock, outstanding stock options under the Company's stock option plans, common stock subject to repurchase by the Company and potential shares to be purchased under the ESPP, 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.

	September 30,	
	2016	2015
Warrants to purchase common stock	149,704	149,704
Common stock options issued and outstanding	3,496,826	2,458,149
Common stock subject to repurchase	6,316	47,308
ESPP shares pending issuance	7,415	7,318
Total	3,660,261	2,662,479

### **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. Early adoption is permitted for annual reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact of the pending adoption of ASU No. 2014-09 on its financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This guidance requires management to perform interim and annual assessments on whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year of the date the financial statements are issued. If such conditions or events exist, certain disclosures are required. ASU No. 2014-15 is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact of the pending adoption of ASU No. 2014-15 on its financial statements and related disclosures.

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 March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718)*. This guidance changes the accounting for certain aspects of stock-based compensation, including income taxes, forfeitures, tax withholding and classification on the statement of cash flows. For public companies, ASU No. 2016-09 is effective for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the impact of the pending adoption of ASU No. 2016-09 on its 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 and liabilities measured at fair value as of September 30, 2016 and December 31, 2015.

	September 30, 2016	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	\$ 12,616,264	\$ 12,616,264	\$ —	\$ —
Corporate debt securities	17,500,086	—	17,500,086	—
Total assets	<u>\$ 30,116,350</u>	<u>\$ 12,616,264</u>	<u>\$ 17,500,086</u>	<u>\$ —</u>

	December 31, 2015	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	\$ 10,221,563	\$ 10,221,563	\$ —	\$ —
Corporate debt securities	24,334,917	—	24,334,917	—
Total assets	<u>\$ 34,556,480</u>	<u>\$ 10,221,563</u>	<u>\$ 24,334,917</u>	<u>\$ —</u>

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:

	<b>Maturity (in years)</b>	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>As of September 30, 2016</b>					
Corporate debt securities	1 or less	\$ 16,741,027	\$ 10,865	\$ (1,887)	\$ 16,750,005
Total		<u>\$ 16,741,027</u>	<u>\$ 10,865</u>	<u>\$ (1,887)</u>	<u>\$ 16,750,005</u>
<b>As of December 31, 2015</b>					
Corporate debt securities	1 or less	\$ 22,635,926	\$ 6,770	\$ (10,677)	\$ 22,632,019
Total		<u>\$ 22,635,926</u>	<u>\$ 6,770</u>	<u>\$ (10,677)</u>	<u>\$ 22,632,019</u>

#### 5. Property and Equipment

Property and equipment consist of the following:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Furniture and fixtures	\$ 333,670	\$ 326,788
Computer equipment and office equipment	116,967	170,946
Leasehold improvements	152,217	142,032
	<u>602,854</u>	<u>639,766</u>
Less accumulated depreciation and amortization	(317,831)	(295,032)
Total	<u>\$ 285,023</u>	<u>\$ 344,734</u>

#### 6. Note Payable

In July 2010, the Company entered into a \$1.0 million promissory note payable to Pfizer Inc. (Pfizer). The note bears interest at 7% per annum, which is paid quarterly, and matures on July 29, 2020. The note payable prohibits the Company from paying cash dividends and is subject to acceleration upon specified events of default as defined in the agreement, including the failure to notify Pfizer of certain material adverse events. In July 2013, the note payable to Pfizer was amended to become convertible into shares of the Company's common stock following the completion of the Company's initial public offering (IPO), at the option of the holder, at a price per share equal to the fair market value of the common stock on the date of conversion.

#### 7. Stockholders' Equity

##### *Common Stock*

In August 2014, the Company entered into an At Market Issuance Sales Agreement (the Sales Agreement) with MLV & Co. LLC (MLV), pursuant to which the Company may sell from time to time, at its option, up to an aggregate of \$50.0 million of shares of its common stock through MLV, as sales agent. Sales of the Company's common stock made pursuant to the Sales Agreement are made on The NASDAQ Global Market (Nasdaq) under the Company's Registration Statement on Form S-3, filed with the SEC on August 14, 2014 and declared effective by the SEC on August 25, 2014, 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 MLV, on Nasdaq or otherwise, at negotiated prices or at prices related to the prevailing market price. Under the terms of the Sales Agreement, MLV may not engage in any proprietary trading or trading as principal for MLV's own account. MLV has agreed to use commercially reasonable efforts consistent with its normal trading and sales practices to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company has agreed to pay a commission rate equal to up to 3% of the gross sales price per share sold. The Company has also agreed to provide MLV with customary indemnification and contribution rights. During the nine months ended

September 30, 2016, the Company sold 5,286,403 shares of its common stock pursuant to the Sales Agreement at a weighted average price per share of \$ 2.29 and received net proceeds of \$ 11.8 million, after deducting offering-related transaction costs and commissions.

### **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 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 and the Lender Warrants will expire on May 30, 2018 and July 3, 2023, respectively.

### **Stock Options**

The following table summarizes the Company's stock option activity under all stock option plans for the nine months ended September 30, 2016:

	<b>Total Options</b>	<b>Weighted- Average Exercise Price</b>
Balance at December 31, 2015	2,464,849	\$ 6.54
Granted	1,132,500	1.96
Exercised	(1,212)	1.24
Cancelled	(99,311)	8.18
Balance at September 30, 2016	<u>3,496,826</u>	<u>\$ 5.01</u>

### **Stock-Based Compensation**

The Company recorded stock-based compensation of \$0.7 million and \$0.8 million for the three months ended September 30, 2016 and 2015, respectively, and \$2.5 million and \$2.6 million for the nine months ended September 30, 2016 and 2015, respectively.

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

The following shares of common stock were reserved for future issuance at September 30, 2016:

Warrants to purchase common stock	149,704
Common stock options issued and outstanding	3,496,826
Common stock authorized for future option grants	556,773
Common stock authorized for the ESPP	565,364
Total	<u>4,768,667</u>

## **8. 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 \$32,784 in 2015 to \$39,268 in 2020. Future minimum payments under this noncancelable operating lease total \$1.7 million at September 30, 2016.

Rent expense was \$94,501 and \$97,568 for the three months ended September 30, 2016 and 2015, respectively, and \$283,504 and \$248,641 for the nine months ended September 30, 2016 and 2015, respectively.

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.

#### **9. Subsequent Events**

Subsequent to the quarter ending September 30, 2016 through the date of this filing, the Company sold 869,318 shares of its common stock pursuant to the Sales Agreement at a weighted average price per share of \$2.04 and received net proceeds of \$1.7 million, after deducting offering-related transaction costs and commissions.

## 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, 2015 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 11, 2016.*

### 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, emricasan has the potential to interrupt the progression of liver disease and potentially provide treatment options in multiple areas of liver disease. To date, emricasan has been studied in over 650 subjects in 16 clinical trials across a broad range of liver disease etiologies and stages of progression. Preclinical studies and clinical trials have yielded compelling results that suggest emricasan may have clinical utility in slowing or reversing progression of liver disease regardless of the original cause of the disease.

We plan to focus on advancing toward initial registration of emricasan for patients with cirrhosis due to nonalcoholic steatohepatitis, or NASH, with parallel development toward registration of emricasan for patients with NASH fibrosis. In February 2016, we announced that the U.S. Food and Drug Administration, or the FDA, granted Fast Track designation to the emricasan development program for the treatment of liver cirrhosis caused by NASH. The Fast Track program provides greater access to the FDA in order to expedite review of drugs that have demonstrated the potential to treat serious or life-threatening conditions.

We plan to conduct a set of parallel trials, the ENCORE trials, designed to evaluate multiple doses of emricasan over various treatment durations in chronic liver disease of different etiologies and disease stages. We are continuing with our plan to initiate the following emricasan clinical trials as resources permit and expect top-line results to be available periodically beginning in 2018:

- ENCORE-PH: A randomized, double-blind, placebo-controlled Phase 2b clinical trial that we initiated in November 2016 to evaluate the effect of emricasan in reducing hepatic venous pressure gradient, or HVPG, in approximately 240 compensated or early decompensated NASH cirrhosis patients with severe portal hypertension, established by baseline HVPG values of 12mmHg or higher. Patients will be randomized 1:1:1:1 to receive 5 mg of emricasan, 25 mg of emricasan, 50 mg of emricasan, or placebo twice daily for 24 weeks. The clinical trial is expected to be conducted at approximately 90 U.S. and European clinical sites. This trial is designed to evaluate dosing, efficacy and safety of emricasan in NASH cirrhosis as an integral part of our initial registration strategy. The primary endpoint is the mean change in HVPG from

week 0 to week 24 for each dosing group compared with placebo. Key secondary endpoints include safety and tolerability, dose response, and percentage of patients achieving at least a 20% reduction in HVPG. Top-line results are expected in 2018.

- ENCORE-LF: A planned randomized, double-blind, placebo-controlled clinical trial to assess long-term liver function endpoints of Model for End-Stage Liver Disease score and Child-Pugh-Turcotte score, related serum biomarkers and laboratory parameters associated with liver function, and to collect chronic administration safety information in NASH cirrhosis patients.
- ENCORE-XT: A planned extension clinical trial to continue treatment for at least an additional 18 months, for a total of at least two years, in patients who complete the ENCORE-PH or ENCORE-LF trials, with continued monitoring for efficacy, safety, clinical outcomes and health-related quality of life.
- ENCORE-NF: A Phase 2b clinical trial evaluating emricasan's potential long-term benefits for patients with liver fibrosis resulting from NASH, which we initiated in January 2016. This randomized, double-blind, placebo-controlled clinical trial will evaluate the effect of emricasan in reducing fibrosis and steatohepatitis in approximately 330 patients with NASH fibrosis but not cirrhosis. Patients will be randomized 1:1:1 to receive 5 mg of emricasan, 50 mg of emricasan, or placebo twice daily for 72 weeks. The primary endpoint is a biopsy-based change in fibrosis by at least one stage using the NASH Clinical Research Network Histologic Scoring System, without worsening of steatohepatitis. Top-line results are expected in 2018.

The ENCORE trials are designed to provide further information on doses leading to clinically relevant efficacy, including improvement in biopsy-proven fibrosis and inflammation in patients with NASH fibrosis, and improvement in severe portal hypertension and hepatic function in patients with NASH cirrhosis. The ENCORE trials are also designed to provide safety data to support the initial registration of emricasan for chronic administration in patients with liver cirrhosis. Depending on the strength of the efficacy and safety data, we believe the ENCORE trials could warrant discussions with regulatory agencies regarding potential accelerated approval. However, the decision to pursue such an accelerated approval will depend on multiple factors, including the size of the efficacy and safety database, the strength of the efficacy and safety data, the adequacy of the dose ranging data, and the regulatory agencies' acceptance of a surrogate endpoint for trials of emricasan in patients with liver cirrhosis.

We also have an ongoing double-blind, placebo-controlled Phase 2b clinical trial in approximately 60 post-orthotopic liver transplant recipients with reestablished liver fibrosis or cirrhosis as a result of recurrent hepatitis C virus infection who have successfully achieved a sustained viral response following hepatitis C virus antiviral therapy who will receive 25 mg of emricasan or placebo orally twice daily for two years. This trial was initiated in May 2014 and the primary endpoint in this exploratory proof-of-concept trial is the change in the Ishak Fibrosis Score compared with placebo. Top-line results are expected in the first half of 2018.

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 funded our operations since inception primarily through sales of equity securities and convertible promissory notes.

We have no products approved for sale. We have not generated any revenues to date, and we have incurred significant operating losses since our inception. We have never been profitable and have incurred net losses of \$24.1 million and \$22.3 million in the years ended December 31, 2015 and 2014, respectively, and \$6.9 million and \$20.6 million for the three and nine months ended September 30, 2016, respectively. As of September 30, 2016, we had an accumulated deficit of \$141.5 million.

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 commercialization of emricasan. In August 2014, we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with MLV & Co. LLC, or MLV, pursuant to which we may sell from time to time, at our option, up to an aggregate of \$50.0 million of shares of our common stock in "at-the-market" offerings. As of September 30, 2016, we have sold 5,436,208 shares of our common stock pursuant to the Sales Agreement at a weighted average price per share of \$2.40 and received net proceeds of \$12.4 million, after deducting offering-related transaction costs and commissions. During the three months ended September 30, 2016, we sold 3,093,769 shares of our common stock pursuant to the Sales Agreement at a weighted average price per share of \$2.16 and received net proceeds of \$6.5 million, after deducting offering-related transaction costs and commissions. During the nine months ended September 30, 2016, we sold 5,286,403 shares of our common stock pursuant to the Sales Agreement at a weighted average price per share of \$2.29 and received net proceeds of \$11.8 million, after deducting offering-related transaction costs and commissions.

As of September 30, 2016, we had cash, cash equivalents and marketable securities of \$31.1 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. We will need to raise additional capital to fund further operations, which are expected to include completion of additional clinical trials of emricasan, regulatory filings for emricasan in the United States and the

European Union and the potential commercialization of emricasan. We may obtain additional financing in the future through the issuance of our common stock in future public offerings, including under the Sales Agreement, 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 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***

We currently have no products approved for sale, and we have not generated any revenues to date. We have not submitted any drug candidate for regulatory approval. In the future, we may generate revenues from a combination of milestone payments, reimbursements and royalties in connection with any future collaboration we may enter into with respect to emricasan, as well as product sales from emricasan. However, we do not expect to receive revenues unless and until we receive approval for emricasan or potentially enter into collaboration agreements for emricasan. If we fail to achieve clinical success in the development of emricasan in a timely manner and/or obtain regulatory approval for this drug candidate, 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 \$60.8 million in the development of emricasan through September 30, 2016. Our business model is currently focused on the development of emricasan in various liver diseases 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 drug 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 whether emricasan will be the subject of future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Research and development expenditures will continue to be significant and will increase 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 and future Phase 2 and Phase 3 clinical trials of 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 emricasan receives regulatory approval, we expect to incur increased expenses associated with building a sales and marketing team. 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 coupon interest on our \$1.0 million promissory note payable to Pfizer Inc.

#### ***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, 2016 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, 2015 filed with the SEC on March 11, 2016.

## **Results of Operations**

### ***Comparison of the Three Months Ended September 30, 2016 and 2015***

#### *Research and Development Expenses*

Research and development expenses were \$4.8 million in the three months ended September 30, 2016, as compared to \$4.1 million for the same period in 2015. The increase of \$0.7 million was primarily due to the progression of our ENCORE program.

#### *General and Administrative Expenses*

General and administrative expenses were \$2.1 million in the three months ended September 30, 2016, as compared to \$2.0 million for the same period in 2015. The increase of \$0.1 million was primarily due to higher personnel costs and consulting fees.

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

#### *Interest Income*

Interest income was \$34,000 for the three months ended September 30, 2016, as compared to \$20,000 for the same period in 2015. Interest income consisted of interest earned on our cash, cash equivalents and marketable securities and fluctuates based on changes in cash balances and interest rates.

#### *Interest Expense*

Interest expense was \$18,000 for each of the three-month periods ended September 30, 2016 and 2015 and consisted of interest related to the \$1.0 million promissory note payable to Pfizer Inc.

#### *Other Income (Expense)*

Other income was \$12,000 for the three months ended September 30, 2016, as compared to other expense of \$8,000 for the same period in 2015. Other income (expense) represents 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.

### ***Comparison of the Nine Months Ended September 30, 2016 and 2015***

#### *Research and Development Expenses*

Research and development expenses were \$13.8 million in the nine months ended September 30, 2016, as compared to \$12.1 million for the same period in 2015. The increase of \$1.7 million was primarily due to the progression of our ENCORE program.

### *General and Administrative Expenses*

General and administrative expenses were \$6.9 million in the nine months ended September 30, 2016, as compared to \$6.0 million for the same period in 2015. The increase of \$0.9 million was primarily due to higher personnel costs and higher consulting, legal and accounting fees.

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

#### *Interest Income*

Interest income was \$95,000 for the nine months ended September 30, 2016, as compared to \$49,000 for the same period in 2015. Interest income consisted of interest earned on our cash, cash equivalents and marketable securities and fluctuates based on changes in cash balances and interest rates.

#### *Interest Expense*

Interest expense was \$53,000 for each of the nine-month periods ended September 30, 2016 and 2015 and consisted of interest related to the \$1.0 million promissory note payable to Pfizer Inc.

#### *Other Income (Expense)*

Other income was \$2,000 for the nine months ended September 30, 2016, as compared to other expense of \$10,000 for the same period in 2015. Other income (expense) represents 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.

### **Liquidity and Capital Resources**

We have incurred losses since inception and negative cash flows from operating activities and, as of September 30, 2016, we had an accumulated deficit of \$141.5 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 the Sales Agreement with MLV, pursuant to which we may 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. Sales of our common stock made pursuant to the Sales Agreement are made on The NASDAQ Global Market, or Nasdaq, under our Registration Statement on Form S-3, filed with the SEC on August 14, 2014 and declared effective by the SEC on August 25, 2014, 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 MLV, on Nasdaq or otherwise, at negotiated prices or at prices related to the prevailing market price. Under the terms of the Sales Agreement, MLV may not engage in any proprietary trading or trading as principal for MLV's own account. MLV will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We pay a commission rate equal to up to 3% of the gross sales price per share sold. We have also agreed to provide MLV with customary indemnification and contribution rights. The Sales Agreement may be terminated by us or MLV at any time upon ten days' notice to the other party, or by MLV 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 September 30, 2016, we have sold 5,436,208 shares of our common stock pursuant to the Sales Agreement at a weighted average price per share of \$2.40 and received net proceeds of \$12.4 million, after deducting offering-related transaction costs and commissions.

Although sales of our common stock have taken place pursuant to the Sales Agreement, there can be no assurance that MLV will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than \$75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Sales Agreement, is limited to an aggregate of one-third of our public float. As of November 1, 2016, our public float was 21.7 million shares, the value of which was \$47.0 million based upon the closing price of our common stock of \$2.16 on September 22, 2016. The value of one-third of our public float calculated on the same basis was \$15.7 million.

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.

At September 30, 2016, we had cash, cash equivalents and marketable securities of \$31.1 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. 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:

	<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Net cash used in operating activities	\$ (17,158,408)	\$ (15,697,260)
Net cash provided by (used in) investing activities	5,781,411	(2,018,667)
Net cash provided by financing activities	11,814,524	22,362,193
Net increase in cash and cash equivalents	<u>\$ 437,527</u>	<u>\$ 4,646,266</u>

Net cash used in operating activities was \$17.2 million and \$15.7 million for the nine months ended September 30, 2016 and 2015, respectively. The primary use of cash was to fund our operations related to the development of emricasan.

Net cash provided by investing activities was \$5.8 million for the nine months ended September 30, 2016, 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 \$2.0 million for the nine months ended September 30, 2015, 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 \$11.8 million for the nine months ended September 30, 2016, which consisted primarily of net proceeds from sales of common stock pursuant to the Sales Agreement. Net cash provided by financing activities was \$22.4 million for the nine months ended September 30, 2015, which consisted primarily of net proceeds from our public offering in April 2015 and sales of common stock pursuant to the Sales Agreement.

### **Contractual Obligations and Commitments**

As of September 30, 2016, 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, 2015 filed with the SEC on March 11, 2016.

### **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, 2016, 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, 2015 filed with the Securities and Exchange Commission on March 11, 2016.

### **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 our 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, 2016, 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, 2015 filed with the Securities and Exchange Commission on March 11, 2016.

### 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 following the signature page of this quarterly report on Form 10-Q and is incorporated herein by reference.

**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 8, 2016

/s/ Steven J. Mento, Ph.D.

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

Date: November 8, 2016

/s/ Charles J. Cashion

Charles J. Cashion  
Senior Vice President, Finance,  
Chief Financial Officer and Secretary  
(principal financial and accounting officer)

## EXHIBIT INDEX

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
4.1(2)	Specimen Common Stock Certificate
4.2(3)	First Amended and Restated Investor Rights Agreement, dated February 9, 2011
4.3(3)	Form of Warrant issued to investors in the Registrant's 2013 bridge financing
4.4(2)	Form of Warrant issued to lenders under the Loan and Security Agreement, dated July 3, 2013, by and among the Registrant, Oxford Finance LLC, Silicon Valley Bank and the other lenders party thereto
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 1, 2013.

(2) Incorporated by reference to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (Registration No. 333-189305), filed with the SEC on July 8, 2013.

(3) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (Registration No. 333- 189305), filed with the SEC on June 14, 2013.

\* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are 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.



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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2016

/s/ Steven J. Mento, Ph.D.

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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, Charles J. Cashion, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2016

/s/ Charles J. Cashion

Charles J. Cashion  
Senior Vice President, Finance,  
Chief Financial Officer and Secretary  
(principal financial and accounting 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, 2016, 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 8, 2016

/s/ Steven J. Mento, Ph.D.

Steven J. Mento, Ph.D.

President and Chief 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, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Charles J. Cashion, Senior Vice President, Finance, Chief Financial Officer and Secretary 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 8, 2016

/s/ Charles J. Cashion

Charles J. Cashion  
Senior Vice President, Finance,  
Chief Financial Officer and Secretary

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.