Conatus Pharmaceuticals Inc.
Form 10-Q
November 06, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM TO

Commission file number: 001-36003

CONATUS PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	20-3183915
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
16745 W. Bernardo Dr., Suite 200 San Diego, CA (Address of Principal Executive Offices)	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 x 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 x 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 ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of November 2, 2015, the registrant had 19,867,773 shares of common stock ($0.0001 par value) outstanding.

CONATUS PHARMACEUTICALS INC.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS 3

Condensed Balance Sheets 3

Condensed Statements of Operations and Comprehensive Loss 4

Condensed Statements of Cash Flows 5

Notes to Condensed Financial Statements 6

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS 13

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 20

ITEM 4. CONTROLS AND PROCEDURES 20

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS 22

ITEM 1A. RISK FACTORS 22

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS 24

ITEM 3. DEFAULTS UPON SENIOR SECURITIES 25

ITEM 4. MINE SAFETY DISCLOSURES 25

ITEM 5. OTHER INFORMATION 25

ITEM 6. EXHIBITS 25

SIGNATURES 26

EXHIBIT INDEX 27

2

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Conatus Pharmaceuticals Inc.

Condensed Balance Sheets

(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$14,558,940	$9,912,674
Marketable securities	28,903,829	27,159,272
Prepaid and other current assets	879,633	796,818
Total current assets	44,342,402	37,868,764
Property and equipment, net	191,023	237,066
Other assets	77,376	342,051
Total assets	$44,610,801	$38,447,881
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$2,252,531	$3,003,612
Accrued compensation	1,392,271	1,171,621
Total current liabilities	3,644,802	4,175,233
Note payable	1,000,000	1,000,000
Deferred rent	150,623	58,699
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; 19,867,773 shares issued and 19,820,465 shares outstanding, excluding 47,308 shares subject to repurchase, at September 30, 2015; 15,695,834 shares issued and 15,560,614 shares outstanding, excluding 135,220 shares subject to repurchase, at December 31, 2014	1,982	1,556
Additional paid-in capital	154,667,432	129,976,075
Accumulated other comprehensive income (loss)	811	(13,297)
Accumulated deficit	(114,854,849)	(96,750,385)
Total stockholders' equity	39,815,376	33,213,949
Total liabilities and stockholders' equity	$44,610,801	$38,447,881

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,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 4,103,257	$ 4,397,402	$ 12,056,997	$ 11,515,068
General and administrative	1,958,078	2,018,835	6,033,739	5,451,770
Total operating expenses	6,061,335	6,416,237	18,090,736	16,966,838
Other income (expense):				
Interest income	19,680	11,989	49,076	48,105
Interest expense	(17,500)	(17,500)	(52,500)	(52,500)
Other expense	(8,391)	(15,412)	(10,304)	(12,307)
Total other expense	(6,211)	(20,923)	(13,728)	(16,702)
Net loss	(6,067,546)	(6,437,160)	(18,104,464)	(16,983,540)
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities	10,702	(8,896)	14,108	(18,245)
Comprehensive loss	$ (6,056,844)	$ (6,446,056)	$ (18,090,356)	$ (17,001,785)
Net loss per share, basic and diluted	$ (0.31)	$ (0.42)	$ (0.99)	$ (1.10)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	19,668,287	15,508,477	18,209,871	15,455,056

See accompanying notes to condensed financial statements.

Conatus Pharmaceuticals Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$(18,104,464)	$(16,983,540)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	50,738	21,407
Stock-based compensation expense	2,574,379	1,565,895
Amortization of premium on marketable securities	283,523	458,850
Changes in operating assets and liabilities:		
Prepaid and other current assets	(82,815)	(250,690)
Other assets	—	(62,981)
Accounts payable and accrued expenses	(754,244)	1,636,245
Accrued compensation	243,699	(43,769)
Deferred rent	91,924	23,403
Net cash used in operating activities	(15,697,260)	(13,635,180)
Investing activities		
Maturities of marketable securities	44,724,000	46,654,000
Purchase of marketable securities	(46,737,972)	(25,539,445)
Capital expenditures	(4,695)	(197,923)
Net cash (used in) provided by investing activities	(2,018,667)	20,916,632
Financing activities		
Proceeds from issuance of common stock, net of offering costs	22,313,252	—
Deferred public offering costs	—	(190,156)
Proceeds from stock issuances under employee stock purchase plan and exercise of stock options	48,941	74,885
Net cash provided by (used in) financing activities	22,362,193	(115,271)
Net increase in cash and cash equivalents	4,646,266	7,166,181
Cash and cash equivalents at beginning of period	9,912,674	4,158,953
Cash and cash equivalents at end of period	$14,558,940	$11,325,134
Supplemental disclosure of cash flow information:		
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, 2015, 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, 2015, had an accumulated deficit of $114.9 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 consolidated financial statements and the notes thereto for the year ended December 31, 2014 included in the Company's annual report on Form 10-K filed with the SEC on March 13, 2015.

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, 2015 and 2014.

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, 2015.

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, 2014, 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, 2015. 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, 2014, 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:

	September 30,	
	2015	2014
Warrants to purchase common stock	149,704	149,704
Common stock options issued and outstanding	2,458,149	1,663,752
Common stock subject to repurchase	47,308	157,543
ESPP shares pending issuance	7,318	—
Total	2,662,479	1,970,999

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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.

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, 2015 and December 31, 2014.

		Fair Value Measurements Using Quoted Prices in		
	September 30, 2015	Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds	$13,038,958	$13,038,958	$ —	$ —
Corporate debt securities	29,855,520	—	29,855,520	—
Total assets	$42,894,478	$13,038,958	$ 29,855,520	$ —

		Fair Value Measurements Using		
	December 31, 2014	Quoted Prices in Active Markets for Identical	Significant Other Observable Inputs	Significant Unobservable Inputs
		Assets (Level 1)	Inputs (Level 2)	(Level 3)

		Assets (Level 1)		
Assets				
Money market funds	$6,998,111	$6,998,111	$ —	$ —
Municipal bonds	70,000	—	70,000	—
Corporate debt securities	28,589,331	—	28,589,331	—
Total assets	$35,657,442	$6,998,111	$ 28,659,331	$ —

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:

As of September 30, 2015	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	$28,903,018	$ 9,678	$ (8,867)	$28,903,829
Total		$28,903,018	$ 9,678	$ (8,867)	$28,903,829

As of December 31, 2014	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	1 or less	$25,795,008	$ 1,137	$ (9,223)	$25,786,922
Corporate debt securities	1 - 2	1,307,561	—	(5,211)	1,302,350
Municipal bonds	1 or less	70,000	—	—	70,000
Total		$27,172,569	$ 1,137	$ (14,434)	$27,159,272

5. Property and Equipment

Property and equipment consist of the following:

	Useful Life in Years	September 30, 2015	December 31, 2014
Furniture and fixtures	4	$ 239,788	$ 239,788
Computer equipment and office equipment	4	167,616	162,921
Leasehold improvements	5	61,533	61,533
		468,937	464,242
Less accumulated depreciation and amortization		(277,914)	(227,176)
Total		$ 191,023	$ 237,066

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 July 2013, the Company completed the IPO of 6,000,000 shares of common stock at an offering price of $11.00 per share. The Company received net proceeds of $58.6 million, after deducting underwriting discounts and commissions

and offering-related transaction costs.

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 three months ended September 30, 2015, the Company sold 149,805 shares of its common stock pursuant to the Sales Agreement at a weighted average price per share of $6.05 and received net proceeds of $0.6 million, after deducting offering-related transaction costs and commissions. The Company incurred legal and accounting transaction costs of $0.3 million in connection with the commencement of the Sales Agreement, which were recorded in other assets on the balance sheet at June 30, 2015, and were reclassified to additional paid-in capital upon the first sale of common stock pursuant to the Sales Agreement.

In April 2015, the Company completed a public offering of 4,025,000 shares of its common stock at a public offering price of $5.75 per share. The shares were registered pursuant to the Registration Statement on Form S-3 filed on August 14, 2014. The Company received net proceeds of $21.4 million, after deducting underwriting discounts and commissions and offering-related transaction costs.

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, 2015:

	Total Options	Weighted-Average Exercise Price
Balance at December 31, 2014	1,859,034	$ 6.84
Granted	772,250	6.19
Exercised	(21,029)	1.04
Cancelled	(152,106)	7.92
Balance at September 30, 2015	2,458,149	$ 6.61

Stock-Based Compensation

The Company recorded stock-based compensation of $0.8 million and $0.7 million for the three months ended September 30, 2015 and 2014, respectively, and $2.6 million and $1.6 million for the nine months ended September 30, 2015 and 2014, respectively.

Common Stock Reserved for Future Issuance

The following shares of common stock are reserved for future issuance at September 30, 2015:

Warrants to purchase common stock	149,704
Common stock options issued and outstanding	2,458,149
Common stock authorized for future option grants	598,413

Common stock authorized for the ESPP	443,988
Total	3,650,254

8. Commitments

In February 2014, the Company entered into a noncancelable operating lease agreement (the Lease) for certain office space from July 2014 through December 2019 with a renewal option for an additional five years. In May 2015, the Company entered into a first amendment to the Lease for additional office space starting in September 2015 through September 2020. The first amendment also extended the term of the Lease to September 2020. The monthly base rent, including the additional office space, will increase approximately 3% annually from $32,784 in 2015 to $39,268 in 2020. Future minimum payments under this noncancelable operating lease total $2.1 million at September 30, 2015.

Rent expense was $98,000 and $83,000 for the three months ended September 30, 2015 and 2014, respectively, and $249,000 and $173,000 for the nine months ended September 30, 2015 and 2014, 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.

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 consolidated financial statements and notes thereto for the year ended December 31, 2014 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 13, 2015.

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" o 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. To date, emricasan has been studied in over 600 subjects in fifteen clinical trials across a broad range of liver disease etiologies and stages of progression and has demonstrated statistically significant, rapid and sustained reductions in elevated levels of key biomarkers of inflammation and apoptosis that are implicated in the severity and progression of liver disease.

By conducting a comprehensive clinical program to demonstrate the therapeutic benefit of emricasan in patients with liver disease across the spectrum of liver disease, we have identified cirrhotic liver patients as a key patient population for future trials with emricasan. Recently, we reported top-line results from our Phase 2 clinical trial in patients with liver cirrhosis and portal hypertension, or PH. We have two active Phase 2 clinical trials: a Phase 2b clinical trial in post-orthotopic liver transplant, or POLT, recipients with liver fibrosis or cirrhosis post-transplant as a result of recurrent hepatitis C virus, or HCV, infection who have successfully achieved a sustained viral response, or SVR, following HCV antiviral therapy, or POLT-HCV-SVR; and a Phase 2 clinical trial in patients with liver cirrhosis and Model for End-stage Liver Disease, or MELD, scores of 11 to 18.

In September 2014, we initiated the exploratory, open-label Phase 2 PH clinical trial of emricasan in patients with liver cirrhosis due to different etiologies and portal hypertension confirmed by hepatic venous pressure gradient, or HVPG, procedure upon enrollment. Patients received 25 mg of emricasan orally twice daily for 28 days. The PH clinical trial was conducted at nine U.S. sites and enrolled 23 patients, 22 of whom were evaluable, with portal hypertension and compensated liver cirrhosis that was predominantly due to nonalcoholic steatohepatitis, or NASH, or HCV, including patients with active HCV infection and patients who had an SVR to antiviral therapy.

We announced in September 2015 that the PH clinical trial met the following primary endpoints: a) a clinically meaningful and statistically significant change from baseline in HVPG in patients with liver cirrhosis and severe portal hypertension (HVPG ≥12 mmHg); and b) a statistically significant change from baseline in cleaved Cytokeratin 18, or cCK18, a mechanism-specific biomarker of excessive cell death that contributes to chronic inflammation, in the total evaluable patient population. Portal hypertension was confirmed by HVPG measurement > 5 mmHg at baseline and measured again after treatment with 25 mg of emricasan orally twice

daily for 28 days. Patients were divided according to the HVPG therapeutic threshold of 12 mmHg, which indicates more severe portal hypertension. Reducing the HVPG to below 12 mmHg or reducing HVPG by ≥10% or ≥20% has been strongly associated with clinical benefit in this patient population. The HVPG endpoint was analyzed in: a) patients with baseline HVPG values ≥12 mmHg (N=12); b) patients with baseline HVPG values < 12 mmHg (N=10); and c) all evaluable patients (N=22). HVPG measurement was standardized, and tracings were evaluated by a single expert reader not otherwise involved in the PH trial. HVPG decreased by a mean of 3.7 mmHg from the mean baseline of 20.6 mmHg in the higher baseline HVPG group ($p < 0.003$), with 8 of 12 patients achieving a ≥10% decrease, 4 of 12 patients achieving a ≥20% decrease, and 2 of 12 patients achieving reductions below 12 mmHg. The changes from baseline HVPG were not statistically significant in the lower baseline HVPG group (+1.9 mmHg mean increase from mean baseline of 8.1 mmHg; p=0.12) or the total evaluable patient population (-1.1 mmHg from mean baseline of 15.2 mmHg; p=0.26). Sensitivity analysis using an HVPG cutoff of 10 mmHg yielded similar results to the group analysis above. The cCK18 endpoint, analyzed in the total evaluable patient population, showed a statistically significant reduction ($p < 0.03$) from baseline. Consistent with results from prior trials, emricasan was safe and well tolerated in the PH trial, with no dose-limiting toxicities and no drug-related serious adverse events. One subject discontinued the trial early for non-serious adverse events and one subject had three serious adverse events ten days after the last emricasan dose, assessed as unrelated to treatment. There were no significant changes in blood pressure or heart rate. Alanine aminotransferase and aspartate aminotransferase levels decreased significantly in the entire group and in those with an HVPG ≥ 12 mmHg.

In May 2014, we initiated the double-blind, placebo-controlled Phase 2b clinical trial in approximately 60 POLT-HCV-SVR patients with residual fibrosis or cirrhosis, classified as Ishak Fibrosis Score 2-6, who will receive 25 mg of emricasan or placebo orally twice daily for two years. In June 2015, we announced initial pre-treatment biomarker and histology data from the trial, confirming that the underlying mechanisms addressed by emricasan are active and that the target population may be suitable for demonstrating potential histology benefits. The primary endpoint in this exploratory proof-of-concept trial is the change in the Ishak Fibrosis Score compared with placebo. The trial will also evaluate histological markers of inflammation, key serum biomarkers, and the safety and tolerability of emricasan. Top-line results are expected in the first half of 2018.

In September 2014, we initiated the double-blind, placebo-controlled, six-month Phase 2 clinical trial in approximately 80 patients with liver cirrhosis due to different etiologies, mild to moderate liver impairment and a MELD score of 11 to 18 during the screening period. In the first stage, which is double-blind and placebo-controlled, patients were randomized 1:1 to receive either 25 mg of emricasan or placebo orally twice daily for three months. The primary endpoint is change from baseline in cCK18. Secondary endpoints include changes from baseline in MELD score and Child-Pugh-Turcotte, or CPT, status. A variety of laboratory parameters associated with liver synthetic and excretory function, such as serum albumin levels, international normalized ratio, or INR, and total bilirubin levels, will also be evaluated. In the second stage, which is open-label, patients who complete the first stage of the trial, either on treatment or placebo, may receive emricasan for an additional three months. Most of the patients in this trial were classified as CPT-B. Initial results from the first stage of this trial are expected to be available in the fourth quarter of 2015 and to be reported in early 2016. Initial results from the second stage of this trial are expected to be available in the second quarter of 2016.

We are planning future trials for our expected initial registration pathway for emricasan with a focus in patients with liver cirrhosis. Our planned trials include four potential pathways that could eventually lead to marketing approval of emricasan. We believe there is unmet clinical need for cirrhosis patients, and that is a key reason why we have chosen to focus on cirrhosis for our initial registration pathway. In May 2015, we met with the U.S. Food and Drug Administration, or FDA, to discuss potential registration pathways for emricasan, including pathways based on validated surrogate endpoints published by the FDA in conjunction with the American Association for the Study of Liver Diseases that may be suitable for approval in cirrhosis, and received feedback on the proposed patient populations and methods of measuring and analyzing these endpoints. We subsequently developed a registration strategy with an initial focus in cirrhosis, with additional supportive long term safety data in patients with NASH fibrosis.

Multiple parallel Phase 2b clinical trials, collectively called the Emricasan, a Caspase Inhibitor, for Evaluation, or ENCORE, trials will evaluate a range of emricasan doses over various treatment durations in patients of different etiologies. We expect to initiate these trials on a staggered basis over the next 15 months and expect top-line results to be available periodically beginning in the first half of 2018:

- ENCORE-PH: A randomized, double-blind, placebo-controlled clinical trial will evaluate the effect of emricasan in reducing HVPG in approximately 160 patients with compensated or early decompensated cirrhosis and severe portal hypertension due to either NASH or HCV-SVR. Treatment will be for six months.
- ENCORE-AC: A randomized, double-blind, placebo-controlled clinical trial will evaluate the effect of emricasan in reducing HVPG in approximately 60 currently abstinent patients with compensated or early decompensated alcoholic cirrhosis and severe portal hypertension. Treatment will be for six months.

- ENCORE-XT: An extension clinical trial will continue treatment for at least an additional 18 months, for a total of at least two years, in patients who complete either the ENCORE-PH trial or ENCORE-AC trial, with an HVPG measurement after the first six months of treatment in the extension trial and continued monitoring for efficacy, safety, clinical outcomes and health-related quality of life.
- ENCORE-LF: A potential randomized, double-blind, placebo-controlled clinical trial, pending results from the ongoing Phase 2 liver cirrhosis trial, will assess long-term liver function endpoints of MELD and CPT, related serum biomarkers and laboratory parameters associated with liver function, and will collect chronic administration safety information in patients with compensated cirrhosis and clinically significant portal hypertension.
- ENCORE-NF: A randomized, double blind, placebo-controlled clinical trial will evaluate the effect of emricasan in reducing fibrosis and steatohepatitis in approximately 300 patients with NASH fibrosis but not cirrhosis. Treatment will be for 18 months. The primary endpoint will be a biopsy-based change in fibrosis by at least one stage using the NASH Clinical Research Network Histologic Scoring System, without worsening of steatohepatitis.

The ENCORE trials are designed to provide statistically significant and clinically relevant efficacy data, dosing confirmation, and safety data to support chronic administration. We believe the combined ENCORE trials will support the design of Phase 3 efficacy and safety trials. We believe the ENCORE trials could warrant discussions with regulatory agencies regarding potential accelerated approval if the resulting efficacy and safety data are sufficiently robust. 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 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.

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 consolidated net losses of $22.3 million and $15.6 million in the years ended December 31, 2014 and 2013, respectively, and $6.1 million and $18.1 million for the three and nine months ended September 30, 2015, respectively. As of September 30, 2015, we had an accumulated deficit of $114.9 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, 2015, we have sold 149,805 shares of our common stock pursuant to the Sales Agreement at a weighted average price per share of $6.05 and received net proceeds of $0.6 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.

As of September 30, 2015, we had cash, cash equivalents and marketable securities of $43.5 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 $42.8 million in the development of emricasan through September 30, 2015. 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 in 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, or GAAP. 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, 2015 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, 2014 filed with the SEC on March 13, 2015.

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and 2014

Research and Development Expenses

Research and development expenses were $4.1 million in the three months ended September 30, 2015, as compared to $4.4 million for the same period in 2014. The decrease of $0.3 million was primarily due to a decrease in external emricasan clinical trial and manufacturing costs, partially offset by an increase in external emricasan preclinical costs.

General and Administrative Expenses

General and administrative expenses were $2.0 million for each of the three-month periods ended September 30, 2015 and 2014.

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

Interest Income

Interest income was $20,000 for the three months ended September 30, 2015, as compared to $12,000 for the same period in 2014. Interest income consisted of interest earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense was $18,000 for each of the three-month periods ended September 30, 2015 and 2014 and consisted of interest related to the $1.0 million promissory note payable to Pfizer Inc.

Other Expense

Other expense was $8,000 for the three months ended September 30, 2015, as compared to $15,000 for the same period in 2014. Other expense represents currency fluctuations in the conversion of account balances held in foreign currencies to U.S. dollars.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Research and Development Expenses

Research and development expenses were $12.1 million in the nine months ended September 30, 2015, as compared to $11.5 million for the same period in 2014. The increase of $0.6 million was primarily due to an increase in external emricasan clinical trial and preclinical costs and higher personnel costs, including noncash stock-based compensation expense, partially offset by a decrease in external emricasan manufacturing costs.

General and Administrative Expenses

General and administrative expenses were $6.0 million in the nine months ended September 30, 2015, as compared to $5.5 million for the same period in 2014. The increase of $0.5 million was primarily due to higher personnel costs,

including noncash stock-based compensation expense.

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

Interest Income

Interest income was $49,000 for the nine months ended September 30, 2015, as compared to $48,000 for the same period in 2014. Interest income consisted of interest earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense was $53,000 for each of the nine-month periods ended September 30, 2015 and 2014 and consisted of interest related to the $1.0 million promissory note payable to Pfizer Inc.

Other Expense

Other expense was $10,000 for the nine months ended September 30, 2015, as compared to $12,000 for the same period in 2014. Other expense represents currency fluctuations in 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, 2015, we had an accumulated deficit of $114.9 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of emricasan and incur additional costs associated with being a public company.

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, 2015, we have sold 149,805 shares of our common stock pursuant to the Sales Agreement at a weighted average price per share of $6.05 and received net proceeds of $0.6 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.

At September 30, 2015, we had cash, cash equivalents and marketable securities of $43.5 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:

	Nine Months Ended September 30,	
	2015	2014
Net cash used in operating activities	$(15,697,260)	$(13,635,180)
Net cash (used in) provided by investing activities	(2,018,667)	20,916,632
Net cash provided by (used in) financing activities	22,362,193	(115,271)
Net increase in cash and cash equivalents	$4,646,266	$7,166,181

Net cash used in operating activities was $15.7 million and $13.6 million for the nine months ended September 30, 2015 and 2014, respectively. The primary use of cash was to fund our operations related to the development of emricasan.

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 investing activities was $20.9 million for the nine months ended September 30, 2014, which consisted primarily of proceeds from maturities of marketable securities, partially offset by cash used to purchase marketable securities and capital expenditures.

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. Our public offering in April 2015 and the Sales Agreement were registered under our Registration Statement on Form S-3 filed on August 14, 2014. For the nine months ended September 30, 2014, net cash used in financing activities was $0.1 million, which consisted of deferred public offering costs related to our Registration Statement on Form S-3 filed on August 14, 2014, partially offset by proceeds from the exercise of stock options.

Contractual Obligations and Commitments

In February 2014, we entered into a lease agreement with The Point Office Partners, LLC for 9,954 rentable square feet of office space located in San Diego, California, with a lease term from July 2014 through December 2019 and a renewal option for an additional five years. In May 2015, we entered into a first amendment to the lease agreement for additional office space of 3,271 rentable square feet starting September 2015 through September 2020. The first amendment to the lease agreement also extended the term of the lease to September 2020. The monthly base rent, including the additional office space, will increase approximately 3% annually from $32,784 in 2015 to $39,268 in 2020.

As of September 30, 2015, there have been no other 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, 2014 filed with the SEC on March 13, 2015.

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, 2015, 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, 2014 filed with the Securities and Exchange Commission on March 13, 2015.

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, 2015, 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, 2014 filed with the Securities and Exchange Commission on March 13, 2015, other than the risk factors below.

Risks Related to Our Business and Industry

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

Our future success depends on our ability to obtain regulatory approval for, and then successfully commercialize our only drug candidate, emricasan. We have not completed the development of any drug candidates. We currently generate no revenues from sales of any drugs, and we may never be able to develop a marketable drug. Emricasan will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote emricasan before we receive regulatory approval from the United States Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

Our initial registration strategy for emricasan is to develop emricasan as a potential treatment for liver cirrhosis. As part of our planned development of emricasan for liver cirrhosis, we also intend to conduct clinical trials in patients with non-alcoholic steatohepatitis, or NASH. In 2015, we completed a Phase 2 clinical trial in liver cirrhosis patients with portal hypertension, or PH, and a Phase 2 trial in patients with non-alcoholic fatty liver disease, or NAFLD, including a subset of patients with NASH. We have two ongoing clinical trials: a Phase 2 clinical trial in patients with liver cirrhosis; and a Phase 2b clinical trial in patients who have developed liver fibrosis post-orthotopic liver transplant, or POLT, due to hepatitis C virus, or HCV, infection and have subsequently achieved sustained viral response, or SVR, following anti-HCV therapy, or POLT-HCV-SVR. We are planning future Phase 2 clinical trials in patients with liver cirrhosis and patients with NASH fibrosis.

In planned Phase 2 clinical trials in patients with liver cirrhosis, we expect to use hepatic venous pressure gradient, or HVPG, Model for End-stage Liver Disease, or MELD, or Child-Pugh-Turcotte, or CPT, status as primary endpoints. These measures have been identified by the FDA as validated, objective measures that potentially could be acceptable as a surrogate clinical endpoint for trials in patients with liver cirrhosis. We believe our planned Phase 2 trial in NASH fibrosis patients may provide supportive data for an initial registration in cirrhosis. There is no guarantee that our current or future clinical trials will be completed on time or at all or that any future clinical trials will commence on time or at all, and the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials. Even if such regulatory authorities agree with the design and implementation of our clinical trials, we cannot guarantee you that such regulatory authorities will not change their requirements in the

future. In addition, even if the planned Phase 2 clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials would likely be required before we submit emricasan for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of emricasan may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of emricasan.

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

If we are unable to obtain regulatory approval of emricasan, we will not be able to commercialize this drug candidate and our business will be adversely impacted.

We have not obtained regulatory approval for any drug candidate. If we fail to obtain regulatory approval to market emricasan, our only drug candidate, we will be unable to sell emricasan, which will significantly impair our ability to generate any revenues. To receive approval, we must, among other things, demonstrate with substantial evidence from clinical trials that the drug candidate is both safe and effective for each indication for which approval is sought, and failure can occur in any stage of development. Satisfaction of the approval requirements typically takes several years, and the time and money needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We have not commenced any Phase 3 clinical trials of emricasan to date, and we cannot predict if, or when, our future clinical trials will generate the data necessary to support an NDA and if, or when, we might receive regulatory approvals for emricasan.

The FDA generally requires two confirmatory clinical trials for approval of an NDA. Under the FDA's Accelerated Approval Program, the FDA may grant "accelerated approval" to product candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments. Accelerated approval provides a pathway for an investigational product to be approved on the basis of adequate and well-controlled clinical studies establishing that the product candidate has an effect on a surrogate endpoint that the FDA considers reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The Accelerated Approval Program does not change the statutory requirements for marketing approval. In addition, as a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. The FDA also generally requires pre-approval of promotional materials as a condition of accelerated approval. In planned Phase 2 trials in patients with liver cirrhosis, we plan to use HVPG as a primary endpoint. Decreasing HVPG has been identified by the FDA as a validated, objective measure that potentially could be acceptable as a surrogate endpoint for clinical trials of patients with liver cirrhosis. We do not know if any of our planned Phase 2 clinical trials could be sufficient for marketing approval or if the FDA will agree with the use of a surrogate endpoint for accelerated approval of emricasan for the treatment of liver cirrhosis. Furthermore, even if one of our planned Phase 2 trials is acceptable as a proof of clinical efficacy by the FDA, the FDA may require a second, Phase 3, confirmatory clinical trial as the basis for approval of emricasan. In addition, in the event emricasan does receive accelerated approval for the treatment of liver cirrhosis, we would be required to conduct one or more post-approval clinical outcomes trials to confirm the clinical benefit of emricasan.

Emricasan could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that emricasan is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that emricasan's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of emricasan may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failure to obtain regulatory approval to market emricasan, which would significantly harm our business, prospects, financial condition and results of operations. In addition, even if we were to obtain approval, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or the imposition of a risk evaluation and mitigation strategy requiring substantial additional post-approval safety measures. Moreover, any approvals that we obtain may not cover all of the clinical indications for which we are seeking approval or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such event, our ability to generate revenues would be greatly reduced and our business would be harmed.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

On July 24, 2013, our Registration Statement on Form S-1 (File No. 333-189305), which registered an aggregate amount of up to $69.0 million of our common stock, was declared effective by the Securities and Exchange Commission for our initial public offering, or IPO. On July 25, 2013, we filed a Registration Statement pursuant to Rule 462(b) (File No. 333-190115), which registered an additional aggregate amount of up to $6.9 million of our common stock. At the closing of our IPO on July 30, 2013, we sold 6,000,000 shares of common stock at an IPO price of $11.00 per share and received gross proceeds of $66.0 million, which resulted in net proceeds to us of $58.6 million, after underwriting discounts and commissions of $4.6 million and offering-related transaction costs of $2.8 million. None of the expenses associated with our IPO were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. Stifel, Nicolaus & Company, Incorporated and Piper Jaffray & Co. acted as joint book-running managers, and JMP Securities LLC and SunTrust Robinson Humphrey, Inc. acted as co-managers for our IPO. On August 23, 2013, the underwriters' 30-day over-allotment option to purchase an additional 900,000 shares of common stock in our IPO expired without being exercised and the IPO terminated.

We intend to use the net offering proceeds to fund the clinical development of emricasan and for working capital and general corporate purposes. Pending use of the net proceeds, we plan to invest the net proceeds from our IPO in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. Through September 30, 2015, the net proceeds have been applied as follows: $20.0 million towards the clinical development of emricasan and $28.2 million towards working capital and general corporate purposes.

Issuer Purchases of Equity Securities

The following table contains information relating to the repurchases of our common stock made by us in the quarter ended September 30, 2015.

	Number of Shares	Maximum Number of

Period	Number of Shares Purchased[1]	Average Price Paid per Share	Purchased As Part of Publicly Announced Plans or Programs	Shares That May Yet Be Purchased Under the Plans or Programs
July 1-31, 2015	—	$—	—	—
August 1-31, 2015	752	0.0825	—	—
September 1-30, 2015	—	—	—	—
Total	752	$0.0825	—	—

[1] Represents unvested shares from the early exercise of employee stock options that were repurchased by us in connection with the termination of an employee, in accordance with the terms of such employee's stock option agreement. We repurchased the shares from the holder at the original issue price. This repurchase was not made pursuant to a publicly announced plan or program to repurchase our stock.

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 6, 2015 /s/ Steven J. Mento, Ph.D.
Steven J. Mento, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: November 6, 2015 /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.