Conatus Pharmaceuticals Inc
Form 10-Q
September 09, 2013
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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 JUNE 30, 2013

¨ **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.)**
4365 Executive Dr., Suite 200	
San Diego, CA	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 558-8130

(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 x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 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 , smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of August 31, 2013, the registrant had 15,607,758 shares of Common Stock ($0.0001 par value) outstanding.

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CONATUS PHARMACEUTICALS INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Conatus Pharmaceuticals Inc.

(a development stage company)

Condensed Consolidated Balance Sheets

(Unaudited)

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 3,280,807	$ 4,036,091
Short-term investments	255,000	3,989,473
Prepaid and other current assets	157,965	76,184
Total current assets	3,693,772	8,101,748
Property and equipment, net	24,264	29,604
Other assets	1,539,452	14,395
Total assets	$ 5,257,488	$ 8,145,747
Liabilities, convertible preferred stock and stockholders deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,353,589	$ 1,087,346
Current portion of notes payable	975,050	
Accrued compensation	370,068	325,555
Total current liabilities	2,698,707	1,412,901
Convertible preferred stock warrant liability	4,103,880	160,345
Note payable	1,000,000	1,000,000
Series A Convertible Preferred Stock, $0.0001 par value; 44,827,538 shares authorized, 32,494,218 and 42,494,218 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	24,708,532	32,208,532
Series B Convertible Preferred Stock, $0.0001 par value; 50,300,000 shares authorized, 30,840,435 and 36,417,224 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	26,680,729	31,699,840
Stockholders deficit:		
Common stock, $0.0001 par value, 120,000,000 shares authorized at June 30, 2013 and December 31, 2012, 1,558,221 shares issued and 1,265,018 shares outstanding, excluding 293,203 shares subject to repurchase at June 30, 2013, 1,207,091 shares issued and 1,052,606 shares outstanding, excluding 154,485 shares subject to repurchase, at December 31, 2012	126	105
Additional paid-in capital	12,049,601	470,982
Accumulated other comprehensive income		551
Deficit accumulated during the development stage	(65,984,087)	(58,807,509)
Total stockholders deficit	(53,934,360)	(58,335,871)
Total liabilities, convertible preferred stock and stockholders deficit	$ 5,257,488	$ 8,145,747

See accompanying notes.

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Conatus Pharmaceuticals Inc.

(a development stage company)

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from July 13, 2005 (Inception) to June 30, 2013
	2013	2012	2013	2012	
Operating expenses:					
Research and development	$ 1,117,096	$ 1,119,145	$ 2,084,874	$ 2,280,775	$ 42,910,022
General and administrative	670,430	649,430	1,419,226	1,399,590	19,535,818
Total operating expenses	1,787,526	1,768,575	3,504,100	3,680,365	62,445,840
Other income (expense):					
Interest income		8,292	132	16,622	1,358,882
Interest expense	(196,244)	(17,500)	(213,744)	(35,000)	(988,573)
Other income (expense)	726	(4,939)	(14,951)	4,315	226,448
Other financing expense	(2,890,258)	(44,193)	(3,437,422)	(35,093)	(4,128,511)
Total other expense	(3,085,776)	(58,340)	(3,665,985)	(49,156)	(3,531,754)
Net loss	(4,873,302)	(1,826,915)	(7,170,085)	(3,729,521)	(65,977,594)
Other comprehensive (income) loss:					
Net unrealized gains (losses) on short-term investments		(313)	(551)	8,383	
Comprehensive loss	$ (4,873,302)	$ (1,827,228)	$ (7,170,636)	$ (3,721,138)	$ (65,977,594)
Reconciliation of net loss to net income (loss) applicable to common stockholders:					
Net loss	$ (4,873,302)	$ (1,826,915)	$ (7,170,085)	$ (3,729,521)	$ (65,977,594)
Gain on extinguishment of convertible preferred stock	11,491,043		11,491,043		11,491,043
Deemed distribution from promissory note issuance	(474,561)		(474,561)		(474,561)
Net income applicable to participating securities	(5,919,404)		(3,846,397)		
Net income (loss) applicable to common stockholders-basic	$ 223,776	$ (1,826,915)	$	$ (3,729,521)	$ (54,961,112)
Net income (loss) per share applicable to common stockholders: (Note 2)					
Basic	$ 0.20	$ (1.81)	$	$ (3.68)	$
Diluted	$ 0.16	$ (1.81)	$	$ (3.68)	$
Weighted average shares outstanding used in computing net income (loss) per share applicable to common stockholders:					
Basic	1,138,695	1,012,117	1,099,830	1,012,117	
Diluted	1,439,211	1,012,117	1,400,229	1,012,117	

See accompanying notes.

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Conatus Pharmaceuticals Inc.

(a development stage company)

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30,		Period From July 13, 2005 (Inception) to June 30, 2013
	2013	2012	
Operating activities			
Net loss	$ (7,170,085)	$ (3,729,521)	$ (65,977,594)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation	5,340	3,907	204,606
Share-based compensation expense	25,916	77,074	423,298
Noncash other financing expense (income)	3,442,335	35,093	4,626,533
Acquisition of in-process research and development			1,250,000
Share-based compensation in lieu of salaries			659,224
Noncash license expense			2,249,999
Amortization (accretion) of premium (discount) on investments	8,922	111,248	(112,694)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(81,781)	(59,159)	(157,965)
Other asset			(14,395)
Accounts payable and accrued expenses	(659,429)	(633,393)	471,753
Accrued compensation	32,939	(267,252)	346,014
Net cash used in operating activities	(4,395,843)	(4,462,003)	(56,031,221)
Investing activities			
Maturities of investments	3,725,000	10,078,000	104,507,865
Purchase of investments		(5,551,386)	(104,650,171)
Cash paid to acquire in-process research and development			(250,000)
Capital expenditures			(228,870)
Net cash provided by (used in) investing activities	3,725,000	4,526,614	(621,176)
Financing activities			
Issuance of promissory notes	1,001,439		7,201,439
Issuance of warrants	113		347
Distribution to wholly owned subsidiary in connection with spin-off of Idun	(500,000)		(500,000)
Issuance of preferred stock for cash, net of offering costs			53,731,226
Deferred public offering costs	(599,385)		(599,385)
Issuance of common stock	13,392	13,085	99,577
Net cash provided by (used in) financing activities	(84,441)	13,085	59,933,204
Net increase (decrease) in cash and cash equivalents	(755,284)	77,696	3,280,807
Cash and cash equivalents at beginning of period	4,036,091	3,072,839	
Cash and cash equivalents at end of period	$ 3,280,807	$ 3,150,535	$ 3,280,807

Supplemental disclosure of cash flow information:

Cash paid for interest	$ 17,500	$ 35,000	$ 187,056
Supplemental schedule of non-cash investing and financing activities:			
Deferred IPO costs	$ 847,982	$	$ 847,982
Conversion of notes payable for preferred stock	$	$	$ 6,736,946
Issuance of warrants in conjunction with debt	$ 506,113	$	$ 2,241,544
Issuance of note payable related to acquisition of in-process research and development	$	$	$ 1,000,000

See accompanying notes.

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Conatus Pharmaceuticals Inc.

(a development stage company)

Notes to Condensed Consolidated 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 June 30, 2013, the Company has devoted substantially all of its efforts to product development, and has not realized revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

The Company has a limited operating history and the sales and income potential of the Company s business and market are unproven. The Company has experienced net losses since its inception, and, as of June 30, 2013, had a net capital deficiency of $53,934,360. 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.

The accompanying condensed consolidated 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 consolidated 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 condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2012 included in the Company s final prospectus filed with the SEC on July 25, 2013 relating to the Company s Registration Statement on Form S-1 (File No. 333-189305) for its initial public offering (IPO).

In July 2013, the Company implemented a 1-for-8.25 reverse stock split of its outstanding common stock. The accompanying condensed consolidated financial statements give retroactive effect to the reverse split for all periods presented.

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 approximately $59.0 million, after deducting underwriting discounts, commissions and estimated offering-related transaction costs.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The condensed consolidated financial statements at December 31, 2012 include all the accounts of the Company and its wholly-owned subsidiary, Idun Pharmaceuticals, Inc. (Idun). All intercompany balances and transactions have been eliminated in consolidation. In January 2013, the assets and rights related to the drug candidate emricasan were distributed from Idun to the Company. Following that distribution, Idun was spun off from the Company.

Use of Estimates

The preparation of consolidated 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.

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Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and investments. 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.

Investments

The Company classifies its investments as available-for-sale and records such assets at estimated fair value in the balance sheet, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss and as a separate component of stockholders deficit. 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 have been no realized gains and losses for the periods ending June 30, 2013, the year ended December 31, 2012, and for the period from July 13, 2005 (inception) to June 30, 2013.

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 year in which the other-than-temporary decline occurred. There have been no other-than-temporary declines in value of short-term investments for the periods ended June 30, 2013, the year ended December 31, 2012, and for the period from July 13, 2005 (inception) to June 30, 2013, 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 accounts payable, accrued expenses, and accrued compensation are reasonable estimates of their fair value because of the short maturity of these items.

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 June 30, 2013.

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Research and Development Expenses

All research and development costs are charged to expense 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, 2012, there are no unrecognized tax benefits included in the consolidated balance sheet that would, if recognized, affect the Company s effective tax rate. The Company has not recognized interest and penalties in the consolidated balance sheets or consolidated statements of operations and comprehensive loss. The Company is subject to U.S. and California taxation. As of December 31, 2012, the Company s tax years beginning 2005 to date are subject to examination by taxing authorities.

Convertible Preferred Stock Warrant Liability

The Company has issued freestanding warrants exercisable to purchase shares of its Series A and Series B convertible preferred stock. These warrants are classified as a liability in the accompanying consolidated balance sheets, as the terms for redemption of the underlying security are outside the Company s control. The Series A convertible preferred stock warrants are recorded at fair value using the Black-Scholes option pricing model. The Series B convertible preferred stock warrants are recorded at fair value using a Monte Carlo model. The fair value of all warrants, except as noted below, is remeasured at each financial reporting date using the Black-Scholes option pricing model with any changes in fair value being recognized in other financing income (expense), a component of other income (expense), in the accompanying statements of operations. The Company ceased the remeasure of the fair value upon exercise of the Series A warrants, and the Series B warrants becoming exercisable for shares of common stock, immediately prior to the completion of the IPO in July 2013.

Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the consolidated 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 investments. Comprehensive gains (losses) have been reflected in the consolidated statements of operations and comprehensive loss for all periods presented.

Net Income (Loss) Per Share

Basic net income (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 income (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 convertible preferred stock, warrants and outstanding stock options under the stock option plan, have been excluded from the computation of diluted net income (loss) per share in the periods in which they would be anti-dilutive.

The following table sets forth the computation of basic and diluted earnings per share:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Numerator:				
Net income (loss) applicable to common stockholders	$ 223,776	$ (1,826,915)	$	$ (3,729,521)
Denominator for basic and diluted net income (loss) per share:				
Weighted average common shares outstanding for basic	1,138,695	1,012,117	1,099,830	1,012,117
Dilutive potential common stock outstanding:				
Unvested stock options outstanding	300,516		300,399	
Weighted average common shares outstanding for diluted	1,439,211	1,012,117	1,400,229	1,012,117

Net income (loss) per share applicable to common stockholders:				
Basic	$ 0.20	$ (1.81)	$	$ (3.68)
Diluted	$ 0.16	$ (1.81)	$	$ (3.68)

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.

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Convertible preferred stock		**9,565,021**		**9,565,021**
Warrants to purchase preferred stock-Series A	**280,675**	**280,675**	**280,675**	**280,675**
Warrants to purchase preferred stock-Series B	**136,236**		**136,236**	
Common stock options		**594,259**		**594,259**
Common stock subject to repurchase		**158,600**		**158,600**
Total	**416,911**	**10,598,555**	**416,911**	**10,598,555**

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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 June 30, 2013 and December 31, 2012.

		Fair Value Measurements Using		
	June 30, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds	**$ 62,247**	**$ 62,247**	**$**	**$**
Municipal bonds	**255,000**		**255,000**	
Total assets	**$ 317,247**	**$ 62,247**	**$ 255,000**	**$**
Liabilities				
Convertible promissory notes	**$ 975,050**			**$ 975,050**
Convertible preferred stock warrant liability	**4,103,880**	**$**	**$**	**4,103,880**
Total liabilities	**$ 5,078,930**	**$**	**$**	**$ 5,078,930**

		Fair Value Measurements Using		
	December 31, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				

Money market funds	$ 3,874,153	$ 3,874,153	$	$
Municipal bonds	260,000		260,000	
Corporate debt securities	3,729,473		3,729,473	
Total assets	$ 7,863,626	$ 3,874,153	$ 3,989,473	$
Liabilities				
Convertible preferred stock warrant liability	$ 160,345	$	$	$ 160,345
Total liabilities	$ 160,345	$	$	$ 160,345

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The Company s short-term investments, 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.

The fair value of the convertible preferred stock warrant liability was determined based on Level 3 inputs and utilized the Black-Scholes option pricing model for the Series A convertible preferred stock warrants. The Series B convertible preferred stock warrants utilized a Monte Carlo model. The Series A fair value measurement used the following inputs at June 30, 2013: Risk-free interest rate of 2.52%, expected dividend yield of zero, expected volatility of 70%, and expected term of 6.75 years. The Series B fair value measurement used the following inputs at June 30, 2013: Risk-free interest rate of 1.40%, expected dividend yield of zero, expected volatility of 75%, and expected term of 4.8 years. The following table presents activity for the convertible preferred stock warrant liability measured at fair value using significant unobservable Level 3 inputs during the years ended December 31, 2012 and the six months ended June 30, 2013.

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2011	$ 68,786
Changes in fair value reflected as other financing expense	91,559
Balance at December 31, 2012	160,345
Issuance of preferred stock warrants	506,113
Changes in fair value reflected as other financing expense	3,437,422
Balance at June 30, 2013	$ 4,103,880

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4. Investments

The Company invests its excess cash in money market funds and debt instruments of financial institutions, corporations, and municipal bonds. The following tables summarize the Company s short-term investments:

As of June 30, 2013	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Municipal bonds	1 or less	$ 255,000	$	$	$ 255,000
Total		$ 255,000	$	$	$ 255,000

5. Property and Equipment

Property and equipment consist of the following:

	Useful Life In Years	June 30, 2013	December 31, 2012
Furniture and fixtures	4	$ 112,876	$ 112,876
Computer equipment and office equipment	4	95,199	95,199
Leasehold improvements	4	3,645	3,645
		211,720	211,720
Less accumulated depreciation and amortization		(187,456)	(182,116)
		$ 24,264	$ 29,604

6. Notes Payable

In July 2010, the Company entered into a $1,000,000 promissory note payable to Pfizer Inc. 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 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.

In May 2013, the Company entered into a note and warrant purchase agreement with certain existing investors pursuant to which it sold, in a private placement, an aggregate of $1.0 million of convertible promissory notes (the 2013 Notes), and issued warrants exercisable to purchase 1,124,026 shares of Series B Preferred Stock (the 2013 Warrants). The 2013 Notes accrue interest at a rate of 6% per annum and are due and payable on the earlier of (1) any date after November 30, 2013 upon which holders of 75% of the outstanding principal amount of all such 2013 Notes demand repayment, or (2) the occurrence of a change of control of the Company, subject in each case to their earlier conversion in the event the Company completes a qualified initial public offering or private placement of debt and/or equity. The 2013 Notes do not provide for any potential adjustments to the stated conversion rates other than in the event of stock splits, stock dividends and recapitalizations. The conversion of the 2013 Notes in the event of a qualified initial public offering or private placement of equity was deemed to be the predominant settlement mechanism. As this predominant settlement mechanism provided for the settlement of a fixed monetary amount in a variable number of equity instruments, the Company concluded that it was appropriate to recognize the 2013 Notes at fair value. The Company valued the 2013 Notes utilizing an estimated cost of debt from publicly available information on issuances of high yield fixed income securities issued by comparable companies. The Company concluded that a 15% discount rate was appropriate, resulting in an initial fair value for the 2013 Notes of approximately $970,000.

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The 2013 Warrants were exercisable for an aggregate of 1,124,026 shares of Series B Preferred Stock at an exercise price of $0.90 per share. Upon completion of the IPO, the 2013 Warrants became exercisable for an aggregate of 136,236 shares of common stock at an exercise price of $7.43 per share. The 2013 Warrants will expire on May 30, 2018. The 2013 Warrants will initially be accounted for as liabilities with changes in fair value recognized within the consolidated statement of operations. The Company determined that the initial value of the 2013 Warrants was $506,000. The 2013 Warrants were valued utilizing a Monte Carlo simulation of various weighted scenarios.

The valuation at the issuance of the 2013 Notes and 2013 Warrants resulted in a deemed distribution in the amount of $474,561 accounted for as a reduction in net income attributable to common stockholders.

Upon completion of the IPO, the 2013 Notes plus accrued interest automatically converted into 91,948 shares of common stock. Upon the completed public offering whereby the 2013 Warrants became exercisable for shares of common stock, the 2013 Warrants will be reclassified into equity at their then fair value.

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7. Stockholders Equity (Deficit)

Common Stock

During 2005, the Company sold 727,273 shares of common stock to founders for approximately $6,000. During 2006, the Company sold 181,818 shares of common stock to founders for approximately $45,000, subject to certain restrictions that have since been released.

Convertible Preferred Stock

Between August 2005 and July 2006, the Company borrowed from certain officers and investors an aggregate principal amount of $1,200,000 under convertible promissory notes. The convertible promissory notes had an annual interest rate of 8% and a conversion premium on principal and accrued interest of 15%. The principal, accrued interest and conversion premium under the convertible promissory notes converted into shares of Series A convertible preferred stock (Series A Preferred Stock) in October 2006, in connection with the initial closing of the Series A Preferred Stock financing.

During 2006, the Company entered into agreements with the founding officers and several investors who collectively purchased 10,160,885 shares of Series A Preferred Stock at $0.75 per share for $5,500,000 in cash, the conversion of the bridge financing noted above, plus related accrued interest and conversion premium of $261,439, and the issuance of preferred stock to employees of approximately $659,224 for services (Initial Closing). Additionally, the Company issued 333,333 shares of the Series A Preferred Stock in satisfaction of its initial license payment to Roche Palo Alto LLC and F. Hoffman-La Roche Ltd. (collectively, Roche) (Note 8).

In May 2007, the Company closed the second round of its Series A Preferred Stock financing, providing the Company with $22,000,000 in gross proceeds from the issuance of an additional 29,333,334 shares of Series A Preferred Stock (Second Closing). Additionally, the Company s Board of Directors determined that the Company had obtained satisfactory completion of certain preclinical studies of its product candidate, which was licensed from Roche, which triggered an additional $3,500,000 payment in cash and $2,000,000, in the form of the issuance of an additional 2,666,666 shares of Series A Preferred Stock to Roche (Note 8).

The holders of the Series A Preferred Stock are entitled to receive noncumulative dividends at a rate of $0.06 per share per annum. The Series A Preferred Stock dividends are payable when and if declared by the Company s Board of Directors. As of June 30, 2013, the Company s Board of Directors has not declared any dividends. The Series A Preferred Stock dividends are payable in preference and in priority to any dividends on common stock.

The holders of the Series A Preferred Stock are entitled to receive liquidation preferences at the rate of $0.75 per share. Liquidation payments to the holders of Series A Preferred Stock have priority and are made in preference to any payments to the holders of common stock.

The shares of Series A Preferred Stock are convertible into shares of common stock at a ratio of 8.25 to 1, at the option of the holder, subject to certain anti-dilution adjustments. Each share of Series A Preferred Stock is automatically converted into common stock immediately upon (i) the Company s sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, in which per share price is at least $22.275 (as adjusted), and the gross cash proceeds are at least $30,000,000 or (ii) the affirmative vote of more than 50% of the holders of the then-outstanding Series A Preferred Stock.

The holders of Series A Preferred Stock are entitled to one vote for each share of common stock into which such Series A Preferred Stock could then be converted; and with respect to such vote, such holder shall have full voting rights and powers equal to the voting rights and powers of the holders of common stock.

Included in the terms of the Series A Preferred Stock agreement were certain rights granted to the holders of the Series A Preferred Stock issued in the Initial Closing which obligated the Company to deliver additional shares of Series A Preferred Stock at a specified price in the future at the potential Second Closing based on the achievement of a milestone or at the option of the holders of the Series A Preferred Stock (the Tranche Right). The Series A Preferred Stock, based on its deemed liquidation terms, is classified outside of stockholder s deficit. Accordingly, the Tranche Right to purchase additional shares was valued and classified as a liability in 2006 and 2007. The carrying value was adjusted at each reporting date for any material changes in its estimated fair value. The estimated fair value was determined using a valuation model which considered the probability of achieving a milestone, if any, the entity s cost of capital, the estimated time period the Tranche Right would be outstanding, consideration received for the instrument with the Tranche Right, the number of shares to be issued to satisfy the Tranche Right, and at what price and any changes in the fair value of the underlying instrument to the Tranche Right. At December 31, 2006, the change in fair value of the Tranche Right was immaterial. In 2007, the change in fair value of the Tranche Right of $530,977 was recorded as other financing expense and the adjusted carrying value of the Tranche Right of $1,827,784 was reclassified to convertible preferred stock on the balance sheet

upon the Second Closing in May 2007.

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In February 2011, the Company closed the first round of its Series B convertible preferred stock (Series B Preferred Stock) financing, providing the Company with $20,000,000 in gross proceeds from the issuance of 22,222,223 shares of Series B Preferred Stock. Upon the first closing, 5,861,667 shares of Series B Preferred Stock were issued upon the conversion of convertible bridge notes and related accrued interest under the terms of the convertible bridge financing agreement. In March 2011, the Company completed an additional closing to a new investor of its Series B Preferred Stock financing, providing the Company with $7,500,000 in gross proceeds from the issuance of an additional 8,333,334 shares of Series B Preferred Stock.

The holders of the Series B Preferred Stock are entitled to receive noncumulative dividends at a rate of $0.072 per share per annum. The Series B Preferred Stock dividends are payable when and if declared by the Company s Board of Directors. As of June 30, 2013, the Company s Board of Directors has not declared any dividends. The Series B Preferred Stock dividends are payable in preference and in priority to any dividends on common stock and Series A Preferred Stock.

The holders of the Series B Preferred Stock are entitled to receive liquidation preferences at the rate of $0.90 per share. Liquidation payments to the holders of Series B Preferred Stock have priority and are made in preference to any payments to the holders of common stock and Series A Preferred Stock.

The shares of Series B Preferred Stock are convertible into shares of common stock at a ratio of 8.25 to 1, at the option of the holder, subject to certain anti-dilution adjustments. Each share of Series B Preferred Stock is automatically converted into common stock immediately upon (i) the Company s sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, in which per share price is at least $22.275 (as adjusted), and the gross cash proceeds are at least $30,000,000 or (ii) the affirmative vote of more than 66.67% of the holders of the then-outstanding Series B Preferred Stock.

The holders of Series B Preferred Stock are entitled to one vote for each share of common stock into which such Series B Preferred Stock could then be converted; and with respect to such vote, such holder shall have full voting rights and powers equal to the voting rights and powers of the holders of common stock.

The Series B Preferred Stock, based on its deemed liquidation terms, is classified outside of stockholders deficit.

On May 30, 2013, 15,576,789 shares of the Company s convertible preferred stock were converted into 1,557,678 shares of common stock (and subsequently subjected to the reverse split of shares into 188,808 shares of common stock) as a result of one preferred stock investor not purchasing a pro rata share of the 2013 Notes. As a result of this transaction, a gain on the extinguishment of preferred stock was recognized as income applicable to common stockholders and an addition to additional paid-in capital in the amount of $11,491,043, which represented the difference between the carrying value of the 15,576,789 shares of convertible preferred stock and the fair value of the 188,808 shares of common stock.

In connection with the IPO in July 2013, all 63,334,653 outstanding shares of convertible preferred stock converted into an aggregate of 7,676,914 shares of common stock.

Warrants

The Company issued warrants to purchase a total of 2,333,320 shares of Series A Preferred Stock in conjunction with a convertible bridge financing in 2010 and issued the 2013 Warrants in conjunction with a convertible bridge financing in 2013. The Company accounts for the warrants as a liability as they are exercisable for shares of preferred stock that is classified outside of permanent equity. The convertible preferred stock warrant liability is required to be recorded at fair value at the grant date of the warrants and the carrying value adjusted at each reporting date. The Company revalued the warrants at June 30, 2013 and 2012, and recorded the change in the value of the warrants of $2,890,258 for the three months ended June 30, 2013 and $3,437,422 for the six months ended June 30, 2013 as other financing expense. The change in the value of the warrants was $44,193 for the three months ended June 30, 2012 and $35,093 for the six months ended June 30, 2012 and recorded as other financing expense. The Series A warrants converted to 280,675 shares of common stock as a result of the net exercise of such warrants at the IPO. Upon the completion of the IPO, the 2013 Warrants became exercisable for an aggregate of 136,236 shares of common stock at an exercise price of $7.43 per share. Following the IPO, the 2013 Warrants will be reclassified into equity at their fair value at the time of the completion of the IPO.

Common Stock

The following shares of common stock are reserved for future issuance at June 30, 2013:

Conversion of preferred stock	9,565,021
Convertible preferred stock warrants	430,379
Stock options issued and outstanding	549,411
Authorized for future option grants	20,545
	10,565,356

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The following table summarizes the Company s stock option activity under all stock option plans for the six months ended June 30, 2013:

	Total Options	Weighted-Average Exercise Price
Balance at December 31, 2012	690,223	$ 0.80
Granted	33,635	1.38
Exercised	(162,326)	.08
Cancelled	(12,121)	.08
Balance at June 30, 2013	549,411	1.06

The Company recorded stock-based compensation of $4,498 and $36,007 for the three months ended June 30, 2013 and 2012, respectively, and $25,916 and $77,074 for the six months ended June 30, 2013 and 2012, respectively.

8. Commitments

The Company leases certain office space under a noncancelable operating lease with terms through June 30, 2014. The rent expense for the three months ended June 30, 2013 and 2012 was $38,514 and $37,978, respectively. The rent expense for the six months ended June 30, 2013 and 2012 was $77,028 and $75,688, respectively. Future minimum payments under the aforementioned noncancelable operating lease total $176,520.

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. Under the agreement, the Company may be required to make payments to Pfizer totaling $18.0 million upon the achievement of specified regulatory milestones.

9. Spin-off of Idun Pharmaceuticals, Inc.

In January 2013, the Company spun off its subsidiary Idun to the Company s stockholders. Prior to the spin-off, rights relating to emricasan were distributed to the Company by Idun pursuant to a distribution agreement. The spin-off was conducted as a dividend of all of the outstanding capital stock of Idun to the Company s stockholders. As a result, the Company no longer held any capital stock of Idun. In connection with the spin-off, the Company contributed $500,000 to Idun to provide for Idun s initial working capital requirements. The assets remaining in Idun at the time of the spin-off consisted of cash, intellectual property rights and license and collaboration agreements unrelated to emricasan. Other than the cash of $500,000, none of the assets held by Idun had any historical carrying value at the time of the spin-off. As a result, the Company recognized a reduction in equity as a result of the spin-off of $500,000, representing the carrying value of Idun in the Company s consolidated financial statements at the time of the spin-off.

10. Subsequent Events

In July 2013, the Company entered into a loan and security agreement, or the Credit Facility, with Oxford Finance LLC and Silicon Valley Bank (the Lenders). The Credit Facility provides funding for an aggregate principal amount of up to $15.0 million. The first term loan of the Credit Facility was funded in July 2013 in the amount of $1.0 million. A second term loan of up to $6.0 million will be funded at the Company s request provided such second funding occurs prior to October 28, 2013. A third term loan of up to $8.0 million will also be funded at the Company s request provided that the Company receives positive results from its planned Phase 2b ACLF trial and such third funding occurs prior to June 30, 2014. Each term loan under the Credit Facility bears interest at a fixed annual rate equal to the greater of (i) 7.75% and (ii) the sum of (a) the three-year U.S. Treasury note rate plus (b) 7.40%, as determined on the funding date of each term loan. The Company is required to make interest-only payments on the first term loan through August 1, 2014 with a maturity date of February 1, 2017. If the second and third term loans are funded, the Company will be required to make interest-only payments on those term loans through the first day of the 12th month following the respective funding date of each term loan. All outstanding term loans will begin amortizing at the end of the interest-only period, with monthly principal and interest payments over 30 consecutive months following the interest-only payment period. Upon repayment of each term loan, the Company is required to make a final payment to the Lenders equal to 5% of the original principal amount of such term loan. In connection with the funding of the first term loan under the Credit Facility, the Company issued warrants to the Lenders to purchase up to an

aggregate of 111,112 shares of Series B convertible preferred stock at an exercise price of $0.90 per share (Lender Warrants). The Lender Warrants issued to the Lenders will expire on July 3, 2023. The Lender Warrants will initially be accounted for as liabilities with the changes in fair value recognized within the consolidated statement of operations.

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Upon completion of the IPO, the Lender Warrants became exercisable for an aggregate of 13,468 shares of common stock at an exercise price of $7.43 per share. Following the IPO, the Lender Warrants will be reclassified into equity at their fair value at the time of the completion of the IPO. The Lender Warrants were initially valued at $119,680, and such amount will be recognized as additional expense over the term of the borrowings.

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 approximately $59.0 million, after deducting underwriting discounts, commissions and estimated offering-related transaction costs.

In July 2013, the Company implemented a 1-for-8.25 reverse stock split of its outstanding common stock. The accompanying condensed consolidated financial statements give retroactive effect to the reverse split for all periods presented.

In connection with the IPO, all 63,334,653 outstanding shares of convertible preferred stock automatically converted into an aggregate of 7,676,914 shares of common stock.

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

The following discussion and analysis and the interim 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, 2012 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed with the Securities and Exchange Commission, or SEC, on July 25, 2013, relating to our Registration Statement on Form S-1, as amended (File No. 333-189305), for our initial public offering.

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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, contemplates, believes, estimates, 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 our lead compound, emricasan, for the treatment of patients in orphan populations with chronic liver disease and acute exacerbations of chronic liver disease. To date, emricasan has been studied in over 500 subjects in ten clinical trials. In a randomized Phase 2b clinical trial, emricasan demonstrated a statistically significant, consistent, rapid and sustained reduction in elevated levels of two key biomarkers of inflammation and cell death, alanine aminotransferase, or ALT, and cleaved Cytokeratin 18, or cCK18, respectively, both of which are implicated in the severity and progression of liver disease. Our initial development strategy targets indications for emricasan with high unmet clinical need and orphan patient populations, such as patients with acute-on-chronic liver failure, or ACLF, chronic liver failure, or CLF, and patients who have developed liver fibrosis post-orthotopic liver transplant due to Hepatitis C virus infection, or HCV-POLT.

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We have designed a comprehensive clinical program to demonstrate the therapeutic benefit of emricasan across the spectrum of fibrotic liver disease. We plan to study emricasan in patients with rapidly progressing fibrosis (HCV-POLT) as well as in patients with established liver cirrhosis and decompensated liver disease (ACLF and CLF). In the HCV-POLT population where progression of fibrosis is particularly rapid, we plan to assess whether emricasan can arrest this progression which eventually leads to cirrhosis and ultimately liver failure. If emricasan demonstrates the ability to halt the progression of fibrosis, we believe this could serve as a basis to study emricasan in additional indications in liver disease in the future. Our planned trials in ACLF will evaluate whether emricasan can halt the progression of decompensation to multi-organ failure or death in an acutely decompensating cirrhotic patient population. Our planned trials in CLF will assess whether emricasan can stabilize decompensation and provide patients with chronic decompensation additional time to obtain a liver transplant. Our clinical development plan for emricasan includes a Phase 2b clinical trial in ACLF patients, a Phase 2b clinical trial in CLF patients, and a Phase 2b/3 pivotal trial in HCV-POLT patients. We expect to initiate the Phase 2b ACLF trial and the Phase 2b/3 HCV-POLT trial (currently designated a Phase 3 registration study in the European Union and a Phase 2b study in the United States) in the second half of 2013. Our plans for the HCV-POLT trial may be modified based on, among other things, our analysis of the outcome of the AASLD FDA Workshop on Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Fatty Liver Disease (NAFLD) held in September 2013. We also plan to initiate the Phase 2b CLF trial in the second half of 2014.

We previously conducted the majority of our activities related to emricasan through our wholly-owned subsidiary, Idun Pharmaceuticals, Inc., or Idun, which we acquired from Pfizer Inc. in August 2010. In January 2013, the assets and rights related to emricasan were distributed from Idun to us for no consideration, at which time we spun off Idun, which became an independent company owned by our stockholders at that time. See Certain Relationships and Related Person Transactions. The following information is presented on a consolidated basis to include the accounts of Idun. All intercompany transactions and balances are eliminated in consolidation.

Since our inception, our primary activities have been organizational activities, including recruiting personnel, conducting research and development, including clinical trials and raising capital. To date, we have funded our operations primarily through sales of preferred stock and convertible promissory notes. From inception through June 30, 2013, we have received net proceeds of $61.0 million from such sales.

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 approximately $12.0 million and $8.7 million in the years ended December 31, 2011 and 2012, respectively, and $4.9 million and $7.2 million for the three and six months ended June 30, 2013, respectively. As of June 30, 2013, we had an accumulated deficit of $66 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 eventual commercialization of emricasan. As of June 30, 2013, we had cash, cash equivalents and short-term investments of approximately $3.5 million. In addition, (1) in July 2013, we borrowed $1.0 million under our credit facility entered into in July 2013, and (2) in July 2013, we completed our initial public offering of 6,000,000 shares of common stock at an offering price of $11.00 per share. We received net proceeds of approximately $59.0 million from our initial public offering, after deducting underwriting discounts, commissions and estimated offering-related transaction costs. To fund further operations, we will need to raise additional capital. We may obtain additional financing in the future through the issuance of our common stock in future public offerings, through other equity or debt financings or through collaborations or partnerships with other companies. Although it is difficult to predict future liquidity requirements, we believe that our existing cash, cash equivalents and short-term investments, together with interest thereon, including funds raised in the initial public offering, will be sufficient to fund our operations for at least the next 18 months, including the completion of our planned Phase 2b ACLF trial, Phase 2b/3 HCV-POLT trial and Phase 2b CLF trial. We will need to raise additional funds to complete additional clinical trials of emricasan, to fund regulatory filings for emricasan in the United States and the European Union and for potential commercialization of emricasan. However, 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 debt or equity 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.

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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. In late 2011, we ceased clinical development of a drug candidate, CTS-1027, which we licensed from Roche Palo Alto LLC and F. Hoffman-La Roche Ltd., or collectively Roche, in 2006. In early 2012, the rights to this drug candidate reverted to Roche. Research and development expenses through 2011 were primarily devoted to this drug candidate. Starting in late 2011, research and development expenses have been focused on the development of emricasan. Since acquiring emricasan in 2010, we have incurred approximately $11.0 million in the development of emricasan through June 30, 2013. Our business model is currently focused on the broad 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;
- facilities, depreciation and allocated operating expenses; 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.

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 planned Phase 2b and Phase 3 clinical trials of emricasan, subject to receiving input from regulatory authorities.

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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 trials;
- the number of sites included in the trials;
- the countries in which the trial is 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 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, and business development functions. Other general and administrative expenses include facility costs, patent filing and maintenance costs, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in future periods, reflecting an expanding infrastructure and increased professional fees associated with being a public reporting company.

In addition, 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 and cash equivalents as well as our short-term investments.

Interest Expense

Interest expense consists of coupon interest on our $1.0 million promissory note payable to Pfizer Inc. and interest accrued on the convertible promissory notes payable to certain existing investors issued in May 2013.

Other Income (Expense)

Other income primarily includes a one-time, non-operating transaction associated with the receipt of a federal investment tax credit in 2010.

Other Financing Expense

Other financing expense consists of the revaluation of our convertible preferred stock warrants issued in conjunction with our 2010 and 2013 bridge note financings.

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 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.

While our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements appearing elsewhere in this quarterly report on Form 10-Q, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

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Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our vendor agreements, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time.

Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with preclinical development activities; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. We have not experienced any significant adjustments to our estimates to date. Clinical trial activities were minimal for the years ended December 31, 2011 and 2012, and the six months ended June, 2013.

Share-Based Compensation

We account for share-based compensation by measuring and recognizing compensation expense for all share-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee s requisite service period, which is generally the vesting period. We estimate the fair value of our share-based awards to employees and directors using the Black-Scholes option pricing model. The Black-Scholes model requires the input of subjective assumptions, including the risk-free interest rate, expected dividend yield, expected volatility, expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

We account for stock options granted to non-employees, which primarily consists of members of our board of directors, using the fair value approach. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms.

Convertible Preferred Stock Warrant Liability

We have issued freestanding warrants exercisable for shares of our Series A and Series B convertible preferred stock. These warrants are classified as a liability in the accompanying condensed consolidated balance sheets, as the terms for redemption of the underlying security are outside our control. The Series A warrants are recorded at fair value using the Black-Scholes option pricing model. The Series B warrants are recorded at fair value using a Monte Carlo model. The fair value of all warrants, except as noted below, is remeasured at each financial reporting date using the Black-Scholes option pricing method with any changes in fair value being recognized in other financing income (expense), a component of other income (expense), in the accompanying condensed consolidated statements of operations. We ceased the remeasure of the fair value of the convertible warrant liability upon the exercise of the Series A warrants and conversion of the Series B warrants to common stock warrants, which occurred immediately prior to the completion of our initial public offering on July 30, 2013. Subsequent to such exercise

and conversion, the warrants will be be classified as a component of stockholders equity and will no longer be subject to remeasurement.

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JOBS Act

In April 2012, 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 controls over financial reporting pursuant to Section 404, (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 until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Results of Operations

Comparison of the Three Months Ended June 30, 2013 and 2012

Research and Development Expenses. Research and development expenses were $1.1 million in each of the three months ended June 30, 2013 and 2012.

*General and Administrative Expenses***.** General and administrative expenses were relatively unchanged at $670,000 and $649,000 in the three months ended June 30, 2013 and 2012, respectively.

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

Interest Income. Interest income was $0 and $8,000 for the periods ended June 30, 2013 and 2012, respectively.

Interest Expense. Interest expense was $196,000 and $17,500 for the periods ended June 30, 2013 and 2012. The increase was primarily due to interest and expenses associated with the aggregate of $1.0 million of convertible promissory notes we issued in May 2013.

Other Income (Expense). Other income was $726 for the three months ended June 30, 2013, as compared to other expense of $4,900 for the same period in 2012 caused by currency fluctuation in the conversion of U.S. dollars to pounds sterling.

Other Financing Expense. Other financing expense for the three months ended June 30, 2013 was $2,890,000, while other financing expense for the same period in 2012 was $44,000 . Other financing expense for the two periods represent the revaluation of warrants to purchase Series A convertible preferred stock issued in 2010 as well as the valuations of warrants to purchase Series B convertible preferred stock we issued in May 2013.

Comparison of the Six Months Ended June 30, 2013 and 2012

Research and Development Expenses. Research and development expenses were $2.1 million in the six months ended June 30, 2013, as compared to $2.3 million for the same period in 2012. The change is primarily due to significant preclinical studies that were completed in 2012.

*General and Administrative Expenses***.** General and administrative expenses were unchanged at $1.4 million for each of the six months ended June 30, 2013 and 2012.

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

Interest Income. Interest income was $132 and $17,000 for the six months ended June 30, 2013 and 2012, respectively.

Interest Expense. Interest expense was $214,000 and $35,000 for the periods ended June 30, 2013 and 2012, respectively. The increase was primarily due to interest and expenses associated with the aggregate of $1.0 million of convertible promissory notes we issued in May 2013.

Other Income (Expense). Other expense was $15,000 for the six months ended June 30, 2013, as compared to other income of $4,000 for the same period in 2012. The increase was primarily due to currency fluctuation in the conversion of U.S. dollars to pounds sterling.

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Other Financing Expense. Other financing expense for the six months ended June 30, 2013 was $3.4 million, while other financing expense for the same period in 2012 was $35,000. Other financing expense for the two periods represent the revaluation of warrants to purchase Series A convertible preferred stock we issued in 2010 as well as the valuations of warrants to purchase Series B convertible preferred stock we issued in May 2013.

Liquidity and Capital Resources

We have incurred losses since inception and negative cash flows from operating activities and, as of June 30, 2013, we had an accumulated deficit of $66.0 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.

From our inception through June 30, 2013, we have funded our operations primarily through private placements of equity and convertible debt securities. At June 30, 2013, we had cash, cash equivalents and short-term investments of approximately $3.5 million. In July 2013, we completed our initial public offering of 6,000,000 shares of common stock at an offering price of $11.00 per share. We received net proceeds of approximately $59.0 million, after deducting underwriting discounts, commissions and estimated offering-related transaction costs. 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 debt and equity financing, as well as potential additional 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.

In May 2013, we issued $1.0 million in aggregate principal amount of convertible promissory notes, which notes automatically converted into 91,948 shares of our common stock in connection with the completion of our initial public offering.

In July 2013, we entered into a loan and security agreement, or the credit facility, with Oxford Finance LLC, as collateral agent and a lender, or Oxford, and certain other lenders party thereto from time to time, or the lenders, including Silicon Valley Bank, or SVB. The credit facility provides funding for an aggregate principal amount of up to $15.0 million. The first term loan of the credit facility was funded in July 2013 in the aggregate principal amount of $1.0 million. A second term loan of up to an aggregate principal amount of $6.0 million will be funded at our request (subject to customary conditions for funding) provided that such second funding occurs prior to October 28, 2013. A third term loan of up to an aggregate principal amount of $8.0 million will also be funded at our request (subject to customary conditions for funding) provided that we receive positive results from our planned Phase 2b ACLF clinical trial and such third funding occurs prior to June 30, 2014. The proceeds of the credit facility will be used solely as working capital and to fund our general business requirements. The credit facility is secured by substantially all of our personal property other than our intellectual property, and the term loans extended under the credit facility are evidenced by secured promissory notes issued to each lender.

Each term loan under the credit facility bears interest at a fixed annual rate equal to the greater of (i) 7.75% and (ii) the sum of (a) the three-year U.S. Treasury note rate plus (b) 7.40%, as determined on the funding date of each term loan. We are required to make interest-only payments on the first term loan through August 1, 2014. If the second and third term loans are funded, we are required to make interest-only payments on these term loans through the first day of the 12th month following the respective funding date of each term loan. All outstanding term loans under the credit facility will begin amortizing at the end of the interest-only period, with monthly payments of principal and interest being made by us to the lenders in 30 consecutive monthly installments following such interest-only period. The first term loan under the credit facility matures on February 1, 2017, and the second and third term loans each mature on the first day of the 30th month following the end of the applicable interest-only period. Upon repayment of each term loan, we are also required to make a final payment to the lenders equal to 5.0% of the original principal amount of such term loan.

The credit facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage, and maintain at least 51.0% of our deposit, securities and commodities accounts with SVB. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends in cash or making other distributions, making investments, creating liens, selling assets, and suffering a change in control, in each case subject to certain exceptions. Additionally, we have a period of 60 days or more after the closing of the credit facility in order to (i) enter into control agreements for accounts that we may keep open outside of SVB, (ii) close certain other accounts and (iii) enter into a landlord agreement on our leased property and a bailee waiver with a subcontractor. During this post-close period, we are required to maintain an amount of cash in our accounts with SVB of not less than the $1.0 million that the lenders have funded to us on the closing date of the credit facility.

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The credit facility also includes events of default, the occurrence and continuation of which provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the term loans under the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, investor abandonment, impairment in the perfection or priority of each lender s security interest in the collateral, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, our failure to obtain or maintain material governmental approvals, and a final judgment against us in an amount greater than $250,000.

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

	Six Months Ended June 30, (unaudited)	
	2013	2012
Net cash used in operating activities	$ (4,395,843)	$ (4,462,003)
Net cash provided by investing activities	3,725,000	4,526,614
Net cash provided by (used in) financing activities	(84,441)	13,085
Net (decrease) increase in cash and cash equivalents	$ (755,284)	$ 77,696

Net cash used in operating activities was $4.4 million for the six months ended June 30, 2013 and $4.5 million for the same period in 2012. The primary use of cash was to fund our operations related to the development of our drug candidates in each of these periods.

Net cash provided by investing activities was $3.7 million and $4.5 million for the six months ended June 30, 2013 and 2012, respectively. Net cash provided by investing activities during these periods consisted primarily of cash received from the sales and maturities of marketable securities.

Financing activities in the six months ended June 30, 2013 used net cash of $84,000 compared to $13,000 provided during the six months ended June 30, 2012 and consisted of proceeds received from the exercise of stock options in 2012. Net cash used during the six months ended June 30, 2013 included of the distribution to the wholly owned subsidiary in connection with the spin-off of Idun as well as the net proceeds from the issuance of the aggregate of $1.0 million of convertible promissory notes we issued in May 2013 and payment of IPO related expenses.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the Securities and Exchange Commission) 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.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash, cash equivalents and short-term investments as of June 30, 2013 consisted of cash, money market funds, municipal bonds and corporate debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation.

In July 2013, we entered into a loan and security agreement under which we drew down $1.0 million. The interest rate under the credit and security agreement is 8.06%, and there is an interest only period until August 1, 2014, followed by a 29-month principal and interest period. The interest rate is fixed during the repayment term and therefore does not subject us to interest rate fluctuation risk. Future draws on the loan would incur interest at a rate to be determined at the time of loan draw.

Foreign Currency Exchange Risk

We hold certain payroll related funds in pounds sterling and are therefore subject to fluctuations in foreign currency rates for U.S. dollars and pounds sterling in connection with those funds. To date we have not incurred any material effects from foreign currency changes on those funds. Such fluctuations are recorded in Other Income (Expense).

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the six months ended June 30, 2013.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation 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 Internal Controls

Our management, including our principal executive officer and our principal financial officer, does not expect that our disclosure controls and procedures or our internal controls 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 the 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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently party to any material legal proceedings.

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ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, together with the other information contained in this quarterly report on Form 10-Q and in our final prospectus filed with the Securities and Exchange Commission, or SEC, on July 25, 2013, relating to our Registration Statement on Form S-1, as amended (File No. 333-189305), for our initial public offering including our consolidated financial statements and the related notes appearing at the end of our final prospectus, before making your decision whether to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. We have marked with an asterisk (*) those risk factors that reflect material changes from the risk factors included in our final prospectus.

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 FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approvals. Our clinical development plan for emricasan currently includes a Phase 2b clinical trial in patients with acute-on-chronic liver failure, or ACLF, a Phase 2b clinical trial in patients with chronic liver failure, or CLF, and a Phase 2b/3 clinical trial in patients who have developed liver fibrosis post-orthotopic liver transplant due to Hepatitis C virus infection, or HCV-POLT. While the HCV-POLT study is designated a Phase 3 registration study in the European Union, or the EU, and based on feedback from the Committee for Medicinal Products for Human Use, we believe it will support the filing of a marketing authorization application, or MAA, in the EU upon completion, it is designated a Phase 2b study in the United States and we therefore sometimes refer to this trial as the Phase 2b/3 HCV-POLT trial. We plan to seek further discussions with the FDA to determine if the HCV-POLT trial may be used to support the filing of a new drug application, or NDA, in the United States. Our plans for the HCV-POLT trial may be modified based on, among other things, our analysis of the outcome of the AASLD FDA Workshop on Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Fatty Liver Disease (NAFLD) held in September 2013. We cannot guarantee that regulatory authorities in the EU will agree that our Phase 3 HCV-POLT study will qualify as a single registration study in support of an MAA or that the FDA will recognize the results from the HCV-POLT trial in support of an NDA filing in the United States. We expect to initiate the Phase 2b ACLF trial and the Phase 2b/3 HCV-POLT trial in the second half of 2013 and the Phase 2b CLF trial in the second half of 2014. There is no guarantee that these trials will commence or be completed 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 trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit emricasan for approval. To the extent that the results of the 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 an 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 ACLF, CLF or HCV-POLT are not as significant as we estimate, our business and prospects will be harmed.

Emricasan was the subject of a clinical hold imposed by the FDA while under development by Pfizer Inc. due to a preclinical observation. Although the clinical hold has been lifted, any adverse side effects or other safety risks associated with emricasan could delay or preclude approval of the drug candidate, cause us to suspend or discontinue our clinical trials or limit the commercial profile of emricasan.

When we acquired emricasan from Pfizer in 2010, emricasan was on clinical hold in the United States due to an observation of inflammatory infiltrates in mice that Pfizer saw in a preclinical study and reported to the FDA in 2007. Pfizer performed additional preclinical studies attempting to characterize the nature of the inflammatory infiltrates, but did not carry out a formal carcinogenicity study to evaluate whether or not the infiltrates progressed to cancer. These infiltrates observed in mice were not observed in any other species. In 2008, Pfizer stopped work on the program. After acquiring emricasan, we conducted a thorough internal review of these studies, commissioned several independent experts to review the data and, based on guidance from the FDA, conducted a 6-month carcinogenicity study in the Tg.rasH2 transgenic mouse model, which is known to be predisposed toward tumor development. This study was completed in 2012. There was no evidence of drug-related tumorgenicity in our carcinogenicity study, and after further discussions with the FDA, we were cleared in January 2013 to proceed with our planned HCV-POLT trial, formally lifting emricasan from clinical hold in the United States. Emricasan was never placed on clinical hold outside the United States. We cannot assure you that emricasan will not be placed on clinical hold in the future for similar or unrelated reasons.

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In addition, undesirable side effects caused by emricasan could result in the delay, suspension or termination of our clinical trials by us, the FDA or other regulatory authorities or institutional review boards, or IRBs, for a number of reasons. To date, over 500 subjects have received emricasan in Phase 1 and Phase 2 clinical trials. The most commonly reported treatment-related adverse events in emricasan-treated subjects were upper abdominal pain, dizziness, headache, fatigue, nausea and diarrhea. Although most of the adverse events reported in relation to emricasan in these trials were mild to moderate, results of our anticipated future trials could reveal a high and unacceptable severity and prevalence of these or other side effects, including, potentially, more severe side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of emricasan for any or all targeted indications. In addition, the drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Even if regulatory authorities granted approval of emricasan, if adverse events caused regulatory authorities to impose a restrictive label or if physicians perceptions of emricasan s safety caused them to limit their use of the drug, our ability to generate sufficient sales of emricasan could be limited. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Clinical drug development involves uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. For example, in late 2011 we ceased clinical development of a drug candidate, CTS-1027, for which we had incurred approximately $31.3 million in research and development expenses prior to such time. The results of preclinical studies and early clinical trials of emricasan may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

Emricasan has been the subject of six Phase 1 and four Phase 2 clinical trials. Although we believe emricasan has demonstrated evidence of a beneficial effect in patients with chronic liver disease independent of the cause of disease, we are now seeking to evaluate emricasan in targeted indications within liver disease, including certain indications for which the safety and efficacy of emricasan have not been previously evaluated. Specifically, we expect to initiate a Phase 2b ACLF trial and a Phase 2b/3 HCV-POLT trial in the second half of 2013 and a Phase 2b CLF trial in the second half of 2014. The development program for emricasan to date has focused primarily on the treatment of HCV patients and the evaluation of the drug candidate in liver disease generally. We cannot be certain that any of our planned clinical trials will be successful, and failure in one indication may have negative consequences for the development of emricasan for other indications. For example, any safety concerns observed in our ACLF trials could limit the prospects for regulatory approval for another indication such as HCV-POLT or CLF. Any such failure may harm our business, prospects and financial condition.

The FDA regulatory approval process is lengthy and time-consuming, and if we experience significant delays in the clinical development and regulatory approval of emricasan, our business will be substantially harmed.

We may experience delays in commencing and completing clinical trials of emricasan. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Although we are targeting the initiation of a Phase 2b ACLF trial and a Phase 2b/3 HCV-POLT trial in the second half of 2013 and a Phase 2b CLF trial in second half of 2014, these planned trials may be delayed for a variety of reasons, including delays related to:

- the availability of financial resources for us to commence and complete our planned trials;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting suitable patients to participate in a trial;

having patients complete a trial or return for post-treatment follow-up;

clinical trial sites deviating from trial protocol or dropping out of a trial;

adding new clinical trial sites; or

manufacturing sufficient quantities of our drug candidate for use in clinical trials.

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Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. In addition, significant numbers of patients who enroll in our clinical trials may drop out during the trials as a result of being offered a liver transplant in the case of ACLF and CLF patients or curative therapy for HCV infection in the case of HCV-POLT patients, or otherwise. We believe we have appropriately accounted for such increased risk of dropout rates in our trials when determining expected clinical trial timelines, but we cannot assure you that our assumptions are correct, or that we will not experience higher numbers of dropouts than anticipated, which would result in the delay of completion of such trials beyond our expected timelines.

We could encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of emricasan in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs in the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of emricasan, the commercial prospects for emricasan will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of emricasan.

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 trials of emricasan to date, and we cannot predict if or when our planned clinical trials will generate the data necessary to support an NDA, and if or when we might receive regulatory approvals for 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.

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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, or REMS, 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.

Even if we obtain and maintain regulatory approval for emricasan in one jurisdiction, we may never obtain regulatory approval for emricasan in any other jurisdiction, which would limit our market opportunities and adversely affect our business.

Obtaining and maintaining regulatory approval for emricasan in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval for a drug candidate, comparable regulatory authorities in foreign countries must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. We expect to submit an MAA to the European Medicines Agency, or EMA, for approval of emricasan in the EU. As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of drug candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling, require a REMS or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the EU also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any drug candidate may be withdrawn. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of emricasan will be harmed, which would adversely affect our business, prospects, financial condition and results of operations.

Even if we receive regulatory approval for emricasan, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, emricasan, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with emricasan.

Any regulatory approvals that we receive for emricasan may be subject to limitations on the approved indicated uses for which emricasan may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS in order to approve emricasan, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves emricasan, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for emricasan will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with emricasan, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of emricasan, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

product seizure or detention, or refusal to permit the import or export of emricasan; and

injunctions or the imposition of civil or criminal penalties.

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The FDA s and other regulatory authorities policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of emricasan. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Even if we obtain regulatory approval for emricasan, the product may not gain market acceptance among physicians, patients, tertiary care centers, transplant centers and others in the medical community.

If emricasan is approved for commercialization, its acceptance will depend on a number of factors, including:

- the clinical indications for which emricasan is approved;
- physicians, major operators of tertiary care centers and transplant centers and patients considering emricasan as a safe and effective treatment;
- the potential and perceived advantages of emricasan over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of emricasan as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts.

If emricasan is approved but fails to achieve market acceptance among physicians, patients or others in the medical community, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Coverage and reimbursement may be limited or unavailable in certain market segments for emricasan, which could make it difficult for us to sell emricasan profitably.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor s determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We intend to seek approval to market emricasan in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for emricasan, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval for a drug candidate. In addition, market acceptance and sales of emricasan will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for emricasan and may be affected by existing and future health care reform measures.

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In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under Medicare in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the Healthcare Reform Act, was enacted. The Healthcare Reform Act, among other things, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees on manufacturers of certain branded prescription drugs, requires manufacturers to participate in a discount program for certain outpatient drugs under Medicare Part D and promotes programs that increase the federal government s comparative effectiveness research, which will impact existing government healthcare programs and will result in the development of new programs. An expansion in the government s role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical products.

Other legislative changes have been proposed and adopted in the United States since the Healthcare Reform Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for emricasan, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell emricasan, we may not be able to generate product revenues.

We currently do not have a commercial organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize emricasan, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We expect that the majority of all ACLF, CLF and HCV-POLT patients will be treated at tertiary care centers and transplant centers and therefore can be addressed with a targeted sales force. We intend to build our own commercial infrastructure in North America and the EU to target these centers, but will evaluate opportunities to partner with pharmaceutical companies that have established sales and marketing capabilities to commercialize emricasan in ACLF, CLF and HCV-POLT outside of North America and

Europe. We may also partner with a pharmaceutical company that has global capabilities to evaluate emricasan in non-orphan indications for which we believe it may also be effective.

The establishment and development of our own sales force or the establishment of a contract sales force to market emricasan will be expensive and time-consuming and could delay any commercial launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of emricasan. To the extent we rely on third parties to commercialize emricasan, if approved, we may have little or no control over the marketing and sales efforts of such third parties and our revenues from product sales may be lower than if we had commercialized emricasan ourselves. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize emricasan.

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A variety of risks associated with marketing emricasan internationally could materially adversely affect our business.

We plan to seek regulatory approval for emricasan outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

If we fail to develop and commercialize any other drug candidates, we may be unable to grow our business.

Although we currently have no plans to do so, we may seek to develop and commercialize drug candidates in addition to emricasan, which is currently our only drug candidate. If we decide to pursue the development and commercialization of any additional drug candidates, we may be required to invest significant resources to acquire or in-license the rights to such drug candidates or to conduct drug discovery activities. In addition, any other drug candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, extensive clinical trials and approval by the FDA and applicable foreign regulatory authorities. All drug candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the drug candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that we will be able to acquire, discover or develop any additional drug candidates, or that any additional drug candidates we may develop will be approved, manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. Research programs to identify new drug candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. If we are unable to develop or commercialize emricasan or any other drug candidates, our business and prospects will suffer.

We cannot be certain that emricasan or any other drug candidates that we develop will produce commercially viable drugs that safely and effectively treat liver or other diseases. Even if we are successful in completing preclinical and clinical development and receiving regulatory approval for one commercially viable drug for the treatment of one disease, we cannot be certain that we will also be able to develop and receive regulatory approval for other drug candidates for the treatment of other forms of that disease or other diseases. If we fail to develop a pipeline of potential drug candidates other than emricasan, we will not have any prospects for commercially viable drugs should our efforts to develop and commercialize emricasan be unsuccessful, and our business prospects would be harmed significantly.

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We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we believe that we hold a leading position in our understanding of caspase inhibition related to liver disease, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than emricasan. We believe the key competitive factors that will affect the development and commercial success of our drug candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

There are currently no therapeutic products approved for the treatment of ACLF, CLF or HCV-POLT. There are a number of marketed therapeutics used in each of these diseases to try to remove the underlying cause of the disease and prevent further liver injury. For example, if the liver damage is a result of Hepatitis B virus or HCV infection, marketed antiviral medications may be used to treat the virus that led to liver damage. If the liver damage is a result of alcoholic hepatitis, marketed alcohol addiction drugs may be used. If the liver damage is a result of obesity, diet and exercise may be prescribed along with marketed therapeutics. If the liver damage is a result of non-alcoholic steatohepatitis, or NASH, marketed drugs such as insulin sensitizers (e.g., metformin), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodiol may be used, although none of these are approved for NASH. In addition to the marketed drugs for those indications, there are drugs in development for each of these indications. Although these marketed therapies and those in development may be efficacious, all of them take time to show an effect and as long as the underlying conditions persist there will continue to be damage to the liver. Emricasan is the only therapeutic we are aware of that is being developed specifically to reduce the level of apoptosis in the liver and as a result it may be used with these other therapies. Our estimates of disease prevalence consider the presence of these other treatments.

In addition, the HCV landscape is expected to evolve dramatically over the next five to ten years with the introduction of new interferon-free regimens, which are expected to reach the market as soon as 2015, and next generation interferon-free regimens, which may reach the market by as early as 2016, with greater efficacy and tolerability over the current antiviral therapies. Based on market research we commissioned, we estimate that treatment rates pre-transplantation would need to be 100% and cure rates would have to exceed 97% before the supply of liver transplants would outstrip the need for transplant on an annual basis.

Even if we obtain regulatory approval for emricasan, the availability and price of our competitors products could limit the demand, and the price we are able to charge, for emricasan. We will not achieve our business plan if the acceptance of emricasan is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to emricasan, or if physicians switch to other new drug products or choose to reserve emricasan for use in limited circumstances. Our inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, prospects, financial condition and results of operations.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make emricasan less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

We may not be able to obtain orphan drug exclusivity for emricasan for any indication.*

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the United States, or if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for these types of diseases or conditions will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. If the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers.

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If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines same drug as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug marketing exclusivity rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

We originally applied for orphan drug designation for emricasan for the treatment of fibrosis in HCV-POLT patients in the United States and the EU. We have not yet received the requested orphan designation from the FDA. In the EU, we withdrew the application based on feedback from the applicable regulatory body that emricasan may have efficacy in fibrosis outside of the HCV-POLT patient population. We originally planned to submit applications for orphan drug designations for ACLF in the United States and the EU in the second half of 2013, but it is now more likely that we will wait to submit these applications until after completion of our planned Phase 2b ACLF trial. We cannot assure you that we will be able to obtain orphan drug exclusivity for emricasan in any jurisdiction for the target indications in a timely manner or at all, or that a competitor will not obtain orphan drug exclusivity that could block the regulatory approval of emricasan for several years. If we are unable to obtain orphan drug designation in the United States or the EU, we will not receive market exclusivity which might affect our ability to generate sufficient revenues. If a competitor is able to obtain orphan exclusivity that would block emricasan s regulatory approval, our ability to generate revenues would be significantly reduced which would harm our business prospects, financial condition and results of operations.

We may form or seek strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to emricasan and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for emricasan because it may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view emricasan as having the requisite potential to

demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to emricasan could delay the development and commercialization of emricasan in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our President and Chief Executive Officer, Steven J. Mento, Ph.D., our Senior Vice President, R&D, and Chief Scientific Officer, Alfred P. Spada, Ph.D., and our Senior Vice President, Clinical Research, and Chief Medical Officer, Gary C. Burgess, M.B., Ch.B. M.Med. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations.

Our scientific team has expertise in many different aspects of drug discovery and development. We conduct our operations at our facility in San Diego, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is very intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms. In order to induce valuable employees to remain at Conatus, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

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

Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, our ability to advance the development of emricasan and obtain regulatory approval and potentially commercialize this drug candidate will be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.*

As of August 31, 2013, we had 17 employees, 14 of whom are full-time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, clinical, regulatory, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for emricasan, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize emricasan will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. To date, we have used the services of outside vendors to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development and other drug development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for emricasan or otherwise

advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize emricasan that we develop and, accordingly, may not achieve our research, development and commercialization goals.

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Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture emricasan and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of emricasan could be delayed.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce emricasan. Our ability to obtain clinical supplies of emricasan could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters is located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Effective upon completion of our initial public offering, we adopted a code of business conduct and ethics. However, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If emricasan is approved, we may be subject to healthcare laws, regulation and enforcement. Our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Although we currently do not have any products on the market, if emricasan is approved, once we begin commercializing emricasan, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, false claims, privacy and security and physician sunshine laws and regulations. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

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If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of emricasan.

We face an inherent risk of product liability as a result of the clinical testing of emricasan and will face an even greater risk if we commercialize any products. For example, we may be sued if emricasan allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of emricasan. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for emricasan;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize emricasan; and
- a decline in our share price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry $5.0 million of product liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions, and we may be subject to a product

liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Our Reliance On Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize emricasan and our business could be substantially harmed.

We anticipate that we will engage one or more third-party CROs in connection with our planned Phase 2 and Phase 3 clinical trials for emricasan. We will rely heavily on these parties for execution of our clinical trials, and we will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for drug candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with drug product produced under cGMP regulations and will require a large number of test subjects. Our failure or any failure by our CROs to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval for or successfully commercialize emricasan. As a result, our financial results and the commercial prospects for emricasan would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of emricasan, if approved. The development and commercialization of emricasan could be stopped, delayed or made less profitable if those third parties fail to obtain and maintain regulatory approval of their facilities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture emricasan on a clinical or commercial scale. Instead, we rely on contract manufacturers for such production.

We do not currently have any agreement with a manufacturer to produce the active pharmaceutical ingredient, or API, in emricasan. We acquired quantities of the API from Pfizer as part of our acquisition of the rights to the drug candidate. We believe the quantities we acquired from Pfizer are sufficient to support our planned Phase 2b ACLF trial, Phase 2b/3 HCV-POLT trial and Phase 2b CLF trial. However, we will need to identify and qualify a new third-party manufacturer of API prior to commercialization of emricasan and, if our estimates regarding our supply are incorrect, prior to the completion of our planned clinical trials. Any delay in identifying and qualifying a new manufacturer of API could delay the potential commercialization of emricasan, and, in the event that we do not have sufficient API to complete our planned clinical trials, it could delay such trials.

In addition, we do not currently have a long-term commitment for the production of finished emricasan drug product. Metrics, Inc., a contract manufacturer, has performed formulation and finished goods manufacturing for us based on purchase orders. We expect to continue to purchase finished drug product from Metrics, but currently have no long-term supply commitment with Metrics. If Metrics is unable to produce the amount of finished drug product we need, we may need to identify and qualify other third-party manufacturers of finished drug product in order to complete the clinical development and commercialization of emricasan. Metrics inability to produce the amount of finished drug product we need, or any delay in identifying and qualifying another manufacturer of finished drug product could delay our clinical trials and the potential commercialization of emricasan.

The facilities used by our contract manufacturers to manufacture emricasan must be approved by the applicable regulatory authorities, including the FDA, pursuant to inspections that will be conducted after an NDA or comparable foreign regulatory marketing application is submitted. We do not control the manufacturing process of emricasan and are completely dependent on our contract manufacturing partners for compliance with the FDA s requirements for manufacture of both the active drug substances and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA s strict regulatory requirements, they will not be able to secure or maintain FDA approval for the manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities does not approve these facilities for the manufacture of emricasan or if it withdraws any such approval in the future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for or market emricasan.

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In addition, the manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of emricasan or in the manufacturing facilities in which emricasan is made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of emricasan will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Our Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.*

Our operations began in 2005 and we have only a limited operating history upon which you can evaluate our business and prospects. Our operations to date have been limited to conducting product development activities for emricasan and performing research and development with respect to our clinical and preclinical programs. In addition, as an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. Nor have we demonstrated an ability to obtain regulatory approval for or to commercialize a drug candidate. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing pharmaceutical products.

We have incurred significant operating losses since our inception, including consolidated net losses of $7.2 million and $3.7 million for the six months ended June 30, 2013 and 2012, respectively. As of June 30, 2013, we had an accumulated deficit of $66.0 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital. Our losses have resulted principally from costs incurred in our research and development activities. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our research, development and commercialization activities, including the clinical development and planned commercialization of our drug candidate, emricasan, and incur the additional costs of operating as a public company. In addition, if we obtain regulatory approval of emricasan, we may incur significant sales and marketing expenses. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or whether or when we will become profitable, if ever.

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Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements for the year ended December 31, 2012.

Our report from our independent registered public accounting firm for the year ended December 31, 2012 includes an explanatory paragraph stating that our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited consolidated financial statements, and it is likely that our stockholders will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

We have not generated any revenues to date from product sales. We may never achieve or sustain profitability, which could depress the market price of our common stock, and could cause our stockholders to lose all or a part of their investment.

Our ability to become profitable depends on our ability to develop and commercialize emricasan. To date, we have no products approved for commercial sale and have not generated any revenues from sales of any drug candidate, and we do not know when, or if, we will generate revenues in the future. We do not anticipate generating revenues, if any, from sales of emricasan for at least the next several years and we will never generate revenues from emricasan if we do not obtain regulatory approval for emricasan. Our ability to generate future revenues depends heavily on our success in:

- developing and securing U.S. and/or foreign regulatory approvals for emricasan;
- manufacturing commercial quantities of emricasan at acceptable cost;
- achieving broad market acceptance of emricasan in the medical community and with third-party payors and patients;
- commercializing emricasan, assuming we receive regulatory approval; and
- pursuing clinical development of emricasan in additional indications.

Even if we do generate product sales, we may never achieve or sustain profitability. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of emricasan.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of emricasan, including our planned Phase 2 and Phase 3 clinical trials. If approved, we will require significant additional amounts in order to launch and commercialize emricasan, including building our own commercial capabilities to sell, market, and distribute emricasan in the United States and the EU.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of emricasan or other research and development initiatives. We also could be required to seek collaborators for emricasan at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to emricasan in markets where we otherwise would seek to pursue development or commercialization ourselves.

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

The terms of our credit facility place restrictions on our operating and financial flexibility.

In July 2013, we entered into a loan and security agreement, or the credit facility, with Oxford Finance LLC, or Oxford, and certain other lenders party thereto from time to time, or the lenders, including Silicon Valley Bank, or SVB, that is secured by a lien covering substantially all of our personal property, excluding intellectual property. As of July 8, 2013, the outstanding principal balance under the credit facility was $1.0 million.

The credit facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage, and maintain at least 51.0% of our deposit, securities and commodities accounts with SVB. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends in cash or making other distributions, making investments, creating liens, selling assets, and suffering a change in control, in each case subject to certain exceptions.

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The credit facility also includes events of default, the occurrence and continuation of which provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the term loans under the credit facility, including foreclosure against our properties securing the credit facility, including our cash, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, investor abandonment, impairment in the perfection or priority of each lender s security interest in the collateral, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, our failure to obtain or maintain material governmental approvals, and a final judgment against us in an amount greater than $250,000. Further, if we are liquidated, the lender s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the credit facility, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidate.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidate, or grant licenses on terms unfavorable to us.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.*

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our most recent private placements, other transactions that have occurred over the past three years and our initial public offering, we may have experienced an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2012, we had federal and state net operating loss carryforwards of approximately $52.3 million and $51.2 million, respectively, and federal and state research and development credits of $1.3 million and $745,000, respectively, which could be limited if we experience an ownership change.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At June 30, 2013, we had approximately $3.5 million of cash, cash equivalents and short-term investments. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since June 30, 2013, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Composition-of-matter patents on the active pharmaceutical ingredient and crystalline forms are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter and crystalline forms of emricasan will be considered patentable by the United States Patent and Trademark Office, or the U.S. PTO, courts in the United States, or by the patent offices and courts in foreign countries. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. Some of our patents related to emricasan were acquired from a predecessor owner and were therefore not written by us or our attorneys, and we did not have control over the drafting and prosecution of these patents. Further, the former patent owners might not have given the same attention to the drafting and early prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. In addition, the former patent owners may not have been completely familiar with U.S. patent law, possibly resulting in inadequate disclosure and/or claims. This could result in findings of invalidity or unenforceability of the patents we own or patents issuing with reduced claim scope.

In addition, the patent applications that we own or that we may license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to emricasan is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, emricasan. Further, if we encounter delays in our clinical trials, the period of time during which we could market emricasan under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to emricasan. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the U.S. PTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U.S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a first to file system in the U.S. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

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Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including *inter partes* review and post grant review have been implemented. As stated above, this reform is untried and untested and will bring uncertainty to the possibility of challenge to our patents in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing emricasan. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that emricasan may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of emricasan. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that emricasan may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of emricasan, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize the drug candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize emricasan may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize emricasan. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of emricasan. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize emricasan, which could harm our business significantly.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public

announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Ownership of our Common Stock

The price of our stock may be volatile.*

Prior to our initial public offering, there was no public market for our common stock. Since the commencement of trading in connection with our initial public offering in July 2013 through September 6, 2013, the sale price per share of our common stock on The NASDAQ Global Market has ranged from a low of $8.26 to a high of $11.24. The trading price of our common stock is likely to continue be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this Risk Factors section and elsewhere in this quarterly report on Form 10-Q, these factors include:

- the commencement, enrollment or results of our planned Phase 2 and Phase 3 clinical trials of emricasan or any future clinical trials we may conduct, or changes in the development status of emricasan;
- any delay in our regulatory filings for emricasan and any adverse development or perceived adverse development with respect to the applicable regulatory authority s review of such filings, including without limitation the FDA s issuance of a refusal to file letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for emricasan;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;

adverse developments concerning our manufacturers;

our inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;

our inability to establish collaborations if needed;

our failure to commercialize emricasan;

additions or departures of key scientific or management personnel;

unanticipated serious safety concerns related to the use of emricasan;

introduction of new products or services offered by us or our competitors;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

our ability to effectively manage our growth;

the size and growth, if any, of the ACLF, CLF and HCV-POLT markets and other targeted markets;

our ability to successfully enter new markets;

actual or anticipated variations in quarterly operating results;

our cash position;

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our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

changes in the market valuations of similar companies;

overall performance of the equity markets;

sales of our common stock by us or our stockholders in the future;

trading volume of our common stock;

changes in accounting practices;

ineffectiveness of our internal controls;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

significant lawsuits, including patent or stockholder litigation;

general political and economic conditions; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this Risk Factors section and elsewhere in this quarterly report on Form 10-Q could have a dramatic and material adverse impact on the market price of our common stock.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our credit facility and a promissory note in the principal amount of $1.0 million issued by us to Pfizer Inc. in July 2010. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.*

As of August 31, 2013, our executive officers, directors, 5% stockholders and their affiliates owned approximately 62.2% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interests.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following 2013, the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may qualify as a smaller reporting company which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.*

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The NASDAQ Global Market, or NASDAQ, to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years following their initial public offering. We are taking advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.*

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in the final prospectus for our initial public offering lapse, the trading price of our common stock could decline. As of August 31, 2013, we had outstanding a total of 15,607,758 shares of common stock. Of these shares, only the 6,000,000 shares of common stock sold by us in our initial public offering are freely tradable without restriction in the public market. However, Stifel, Nicolaus & Company, Incorporated and Piper Jaffray & Co., the underwriters for our initial public offering, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to our initial public offering will expire 180 days after July 24, 2013, the date of the final prospectus for our initial public offering. After the lock-up agreements expire, up to an additional 9,607,758 shares of common stock will be eligible for sale in the public market, of which 8,202,260 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of 9,450,940 shares of our common stock (including shares issuable upon exercise of options and warrants) as of August 31, 2013 will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.*

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, our stockholders may be materially diluted by subsequent sales, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2013 incentive award plan, or the 2013 plan, which became effective on the business day prior to the public trading date of our common stock, our management is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under the 2013 plan will automatically increase each year by an amount equal to the least of (1) 1,000,000 shares of our common stock, (2) 5% of the outstanding shares of our common stock as of the last day of our immediately preceding fiscal year, or (3) such other amount as our board of directors may determine. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

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We have broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively.*

Our management will have broad discretion in the application of the net proceeds from our initial public offering. Because of the number and variability of factors that will determine our use of the net proceeds from our initial public offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately improve our operating results or increase the value of our common stock. We expect to use the net proceeds from our initial public offering to fund the clinical development of emricasan and to fund working capital and for general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from our initial public offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.*

Our amended and restated certificate of incorporation and amended and restated bylaws, which became effective in connection with the closing of our initial public offering, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing or cause us to take other

corporate actions desired by certain stockholders. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.*

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If no, or limited, securities or industry analysts cover of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Unregistered Sales of Equity Securities

From April 1, 2013 through June 30, 2013, we issued and sold the equity securities described below.

In May 2013, we issued and sold an aggregate of $1.0 million in principal amount of convertible promissory notes to existing investors. In connection with the issuance of these notes, we issued warrants which are exercisable for an aggregate of 1,124,026 shares of Series B convertible preferred stock at an initial exercise price per share of $0.90, for consideration equal to $0.0001 per warrant share. In connection with the completion of our initial public offering in July 2013, the notes (including accrued interest thereon) automatically converted into 91,948 shares of common stock and the warrants became exercisable for an aggregate of 136,236 shares of common stock, at an exercise price of $7.43 per share.

The securities described in this Item 2 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of the equity securities described above represented to us in connection with their purchase that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 2 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer. No underwriters were involved in the transactions described in this Item 2.

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 SEC for our initial public offering. 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 the offering on July 30, 2013, we sold 6,000,000 shares of common stock at an initial public offering price of $11.00 per share and received gross proceeds of $66.0 million, which resulted in net proceeds to us of approximately $59.0 million, after underwriting discounts and commissions of approximately $4.6 million and offering-related transaction costs of approximately $2.4 million. None of the expenses associated with the initial public offering 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 the offering. On August 23, 2013, the underwriters 30-day over-allotment option to purchase an additional 900,000 shares of common stock in the offering expired without being exercised and the offering 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 this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. There has been no material change in the planned use of proceeds from our initial public offering from that described in our final prospectus filed with the Securities and Exchange Commission on July 25, 2013.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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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.

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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: September 9, 2013

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

President and Chief Executive Officer

(principal executive officer)

Date: September 9, 2013

/s/ Charles J. Cashion
Charles J. Cashion

Senior Vice President, Finance,

Chief Financial Officer and Secretary

(principal financial and accounting officer)

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INDEX TO EXHIBITS

Exhibit Number	Description
3.1[(1)]	Amended and Restated Certificate of Incorporation
3.2[(1)]	Amended and Restated Bylaws
4.1[(3)]	Specimen Common Stock Certificate
4.2[(2)]	First Amended and Restated Investor Rights Agreement, dated February 9, 2011
4.3[(2)]	Form of Warrant issued to investors in the Registrant s 2013 bridge financing
4.4[(3)]	Form of Warrant issued to lenders under the Loan and Security Agreement, dated as of July 3, 2013, by and among the Registrant, Oxford Finance LLC, Silicon Valley Bank and the other lenders party thereto
10.1[(3)]	Fourth Amendment to Office Lease Agreement, dated June 25, 2013, by and between Pacifica Tower LLC, successor in interest to EOP-Plaza at La Jolla, L.L.C., and the Registrant
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 the Registrant s Registration Statement on Form S-1 (Registration No. 333- 189305), filed with the SEC on June 14, 2013.

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

* 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 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.

** Users of this data are advised that pursuant to Rule 406T of Regulation S-T, this XBRL information is being furnished and not filed herewith for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and Sections 11 or 12 of the Securities Act of 1933, as amended, and is not to be incorporated by reference into any filing, or part of any registration statement or prospectus, of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.