ACHILLION PHARMACEUTICALS INC
Form 10-Q
August 07, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

OR

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

For the transition period from _____ to _____

Commission File Number 001-33095

ACHILLION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-2113479**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
300 George Street, New Haven, CT	**06511**
(Address of principal executive offices)	**(Zip Code)**

(203) 624-7000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of August 1, 2013, the registrant had 96,642,564 shares of Common Stock, $0.001 par value per share, outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Achillion Pharmaceuticals, Inc.

Balance Sheets

(in thousands, except per share amounts)

(Unaudited)

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 17,237	$ 18,526
Marketable securities	116,583	46,884
Accounts and other receivables	609	277
Prepaid expenses and other current assets	2,619	2,180
Total current assets	137,048	67,867
Marketable securities	52,352	12,008
Fixed assets, net	1,297	1,247
Deferred financing costs	79	256
Restricted cash	152	152
Total assets	$ 190,928	$ 81,530
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 6,561	$ 4,276
Accrued expenses	6,932	4,510
Current portion of long-term debt	361	350
Total current liabilities	13,854	9,136
Long-term debt	164	347
Total liabilities	14,018	9,483
Commitments and contingencies		
Stockholders Equity:		
Common Stock, $.001 par value; 200,000 shares authorized: 96,638 and 79,626 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	97	80
Additional paid-in capital	531,359	394,675
Accumulated deficit	(354,405)	(322,727)
Accumulated other comprehensive (loss) income	(141)	19
Total stockholders equity	176,910	72,047
Total liabilities and stockholders equity	$ 190,928	$ 81,530

The accompanying notes are an integral part of these financial statements.

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Achillion Pharmaceuticals, Inc.

Statements of Comprehensive Loss

(in thousands, except per share amounts)

(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2013	2012	2013	2012
Revenue	$	$	$	$ 2,489
Operating expenses				
Research and development	16,568	8,979	25,288	17,921
General and administrative	3,545	2,580	6,619	5,318
Total operating expenses	20,113	11,559	31,907	23,239
Loss from operations	(20,113)	(11,559)	(31,907)	(20,750)
Other income (expense)				
Interest income	185	55	263	119
Interest expense	(12)	(23)	(34)	(37)
Net loss	(19,940)	(11,527)	(31,678)	(20,668)
Total comprehensive loss (Note 11)	(20,051)	(11,543)	(31,838)	(20,636)
Basic and diluted net loss per share (Note 5)	$ (0.21)	$ (0.16)	$ (0.35)	$ (0.29)
Weighted average number of shares used in computing basic and diluted net loss per share	96,580	71,211	91,245	70,811

The accompanying notes are an integral part of these financial statements.

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Achillion Pharmaceuticals, Inc.

Statements of Cash Flows

(in thousands)

(Unaudited)

	For the Six Months Ended June 30,	
	2013	2012
Cash flows from operating activities		
Net loss	$ (31,678)	$ (20,668)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	197	209
Non-cash stock based compensation	3,087	1,735
Premium on purchases of marketable securities	(3,077)	(135)
Amortization of premium on marketable securities	956	203
Changes in operating assets and liabilities:		
Accounts and other receivables	(332)	(323)
Prepaid expenses and other assets	(271)	(512)
Accounts payable	2,285	73
Accrued expenses	2,422	714
Deferred revenue		(2,489)
Net cash used in operating activities	(26,411)	(21,193)
Cash flows from investing activities		
Purchases of fixed assets	(238)	(576)
Purchases of marketable securities	(144,947)	(32,845)
Maturities of marketable securities	36,865	54,950
Net cash (used in) provided by investing activities	(108,320)	21,529
Cash flows from financing activities		
Proceeds from sale of common stock, net of issuance costs	133,211	
Proceeds from exercise of stock options	298	1,237
Proceeds from sale of common stock under Employee Stock Purchase Plan	105	88
Borrowings of debt		609
Repayments of debt	(172)	(116)
Net cash provided by financing activities	133,442	1,818
Net increase in cash and cash equivalents	(1,289)	2,154
Cash and cash equivalents, beginning of period	18,526	16,110
Cash and cash equivalents, end of period	$ 17,237	$ 18,264
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 27	$ 33
Supplemental disclosure of noncash financing activities		
Cashless exercise of warrants	$	$ 11,919

The accompanying notes are an integral part of these financial statements.

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Achillion Pharmaceuticals, Inc.

Notes to Financial Statements

(in thousands, except per share amounts)

(Unaudited)

1. Nature of the Business

Achillion Pharmaceuticals, Inc. (the Company) was incorporated on August 17, 1998 in Delaware. The Company was established to discover, develop and commercialize innovative anti-infective drug therapies. The Company is devoting substantially all of its efforts towards product research and development.

The Company incurred losses of $340,543 from inception through June 30, 2013 and had an accumulated deficit of $354,405 at June 30, 2013, which includes preferred stock dividends recognized until the Company s initial public offering in 2006. The Company has funded its operations primarily through the sale of equity securities.

The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to support its current operating plan through at least June 30, 2014. However, the Company s operating plan may change as a result of many factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of sovaprevir, ACH-3102, ACH-2684, and ACH-3422, including additional studies, if any, that may be required to resolve the clinical hold on sovaprevir;
- the scope of and costs associated with entering into cooperative study arrangements, or CSAs, if any, for the collaborative development of its drug candidates in combination with others drug candidates;
- the costs involved in obtaining regulatory approvals for the Company s drug candidates;
- the scope, prioritization and number of programs the Company pursues;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- the Company s ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact its ability to obtain capital in the future;
- the Company s acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to the Company.

In June 2013, the U.S. Food and Drug Administration, or FDA, placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subject drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. The FDA has allowed continued enrollment and treatment of patients in the phase II -007 clinical trial evaluating 12-weeks of sovaprevir in combination with ACH-3102 and ribavirin for patients with treatment-naive genotype 1 HCV. In order to resolve the clinical hold,

the FDA has asked for study reports from two drug-drug interaction studies, an integrated safety analysis of on-going sovaprevir trials, and future development plans and protocols, each of which the Company expects to provide to the FDA in August 2013.

2. Accounting Standards Updates

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. This standard requires additional disclosures regarding the reporting of reclassifications out of accumulated other comprehensive income (AOCI). This ASU is effective for reporting periods beginning after December 15, 2012. The Company evaluated this pronouncement effective January 1, 2013 and determined the further breakout of accumulated other comprehensive income is immaterial to the Company s financial statements.

3. Basis of Presentation

The accompanying unaudited financial statements of the Company should be read in conjunction with the audited financial statements and notes as of and for the year ended December 31, 2012 included in the Company s Annual Report on Form 10-K filed with the SEC on February 20, 2013. The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) for interim financial information, in accordance with the instructions to Form 10-Q and the guidance in Article 10 of Regulation S-X. Accordingly, since they are interim financial statements, the accompanying financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The accompanying financial

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statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair statement of the results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the financial statements and notes thereto. A discussion of the Company s critical accounting policies and management estimates is described in Management s Discussion and Analysis of Financial Condition and Results of Operations included in Part I, Item II of this quarterly report on Form 10-Q.

4. Financing Activities

Public Offering

In February 2013, the Company entered into an underwriting agreement (the Underwriting Agreement) with Citigroup Global Markets, Inc. and Leerink Swann LLC as representatives of the several underwriters named therein (the Underwriters), related to a public offering of shares of the Company s common stock, par value $.001 per share, at a price of $8.40 per share less underwriting discounts and commissions (the Offering). The Company issued and sold to the Underwriters an aggregate of 16,894 shares of common stock in connection with the Offering. The Offering resulted in net proceeds to the Company of $133,211.

5. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated in accordance with ASC 260, *Earnings Per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock options and warrants. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. Securities that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been antidilutive. Potentially dilutive securities were as follows during the six months ended June 30, 2013 and 2012:

	Six Months Ended June 30,	
	2013	2012
Stock Options:		
Weighted average number, in thousands	7,417	6,159
Warrants:		
Weighted average number, in thousands	5,348	8,048

Potentially dilutive securities outstanding as of June 30, 2013 and 2012 are as follows:

	June 30,	
	2013	2012
Options, in thousands	7,902	5,975
Warrants, in thousands	5,348	6,071
Total potentially dilutive securities outstanding, in thousands	13,250	12,046

6. Collaboration Arrangements

GCA Therapeutics, Ltd.

In February 2010, the Company entered into a license agreement (the Agreement) with GCA Therapeutics, Ltd. (GCAT) for elvucitabine, the Company s nucleoside reverse transcriptase inhibitor for the treatment of both hepatitis B virus (HBV) infection and human immunodeficiency virus (HIV) infection. The Agreement was amended and restated in March 2010. The exclusive license grants GCAT the right, through a Chinese joint venture with Tianjing Institute of Pharmaceutical Research, to clinically develop and commercialize elvucitabine in mainland

China, Hong Kong and Taiwan.

Under the terms of the Agreement, GCAT, through a sublicense agreement with a Chinese joint venture, T&T Pharma Co., Ltd., will assume all development and regulatory responsibility and associated costs for elvucitabine. The Company did not receive any payment upon the entry into the agreement. Upon the first commercial sale of a licensed product, GCAT is obligated to pay $100 to the Company. Further, the Company will be eligible to receive royalties up to 15% of net sales in those territories.

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The Company does not believe that the milestone specified under the Agreement is substantive as achievement of the milestone is based solely on the performance of GCAT and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Agreement, it intends to recognize revenue related to the milestone payment upon achievement of the milestone by GCAT. However, there can be no assurance that GCAT will achieve the milestone or that the Company will receive the related revenue. This Agreement shall be effective, unless earlier terminated, until the expiration of the last to expire royalty term.

Ora, Inc.

In October 2012, the Company entered into a license and development agreement (the Ora Agreement) with Ora, Inc. (Ora) for the worldwide development and commercialization of ACH-702 delivered topically or locally. The Ora Agreement was amended in April 2013. Under the terms of the Ora Agreement, Ora will assume development and regulatory responsibility and associated costs for ACH-702. Upon initiation of the agreement, the Company received a one-time license fee of $100, which was recognized as revenue upon the completion of the technology transfer by the Company. The Company is eligible to receive up to $4,000 in development milestones and up to $7,000 in commercialization milestones as well as royalties up to 3.5% of net sales. The Company has no further obligations under the Ora Agreement.

The Ora Agreement includes the right to sublicense any or all of the licensed rights, subject to the Company s approval. Ora shall pay the Company 15% of all up-front licensing payments and any other payment allocated to or received by Ora pursuant to any sublicense agreement granted by Ora under this agreement; provided that such payment is not a royalty on net sales and not a development or commercial milestone already due to Achillion. In December 2012, Ora entered into a sublicense agreement with Taejoon Pharmaceutical Co. for the development of ACH-702.

The Company does not believe that the milestones specified under the Ora Agreement are substantive as achievement of the milestones is based solely on the performance of Ora and its sublicensee(s) and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Ora Agreement, it intends to recognize revenue related to the milestone payments upon achievement of the milestone by Ora or its sublicensee(s). The Ora Agreement shall be effective and, unless earlier terminated, will continue until the last sale of each and every licensed product to an unrelated third party by Ora, its affiliate or sublicensee.

7. Marketable Securities

The Company applies the provisions of Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures,* for financial assets and liabilities measured on a recurring basis which requires disclosure that establishes a framework for measuring fair value and expands disclosures in the financial statements. The guidance requires that fair value measurements be classified and disclosed in one of the three categories:

Level 1: Quoted prices in active markets for identical assets and liabilities that the reporting entity has the ability to access at the measurement date;

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; or

Level 3: Unobservable inputs.

The fair value of the Company s marketable securities of $168,935 and $58,892 as of June 30, 2013 and December 31, 2012, respectively, is valued based on level 2 inputs. The Company s investments consist mainly of U.S. government and agency securities, government sponsored bond obligations and certain other corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. The Company has assessed these as level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available for sale as defined in ASC 320, *Debt and Equity Securities*. Securities are carried at fair value with the unrealized gains (losses) reported as a separate component of stockholders equity within accumulated other comprehensive income.

The unrealized (loss) gain from marketable securities was $(141) and $19 at June 30, 2013 and December 31, 2012, respectively.

As of June 30, 2013 and December 31, 2012, none of the Company s investments were determined to be other than temporarily impaired.

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The following table summarizes the Company s investments:

	June 30, 2013				December 31, 2012			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial Paper	$ 42,633	$ 55		$ 42,688	$ 30,462	$ 29		$ 30,491
Corporate Debt Securities	121,944		(191)	121,753	26,912		(11)	26,901
Government and Agency Securities	4,499		(5)	4,494	1,499	1		1,500
Total	$ 169,076	$ 55	(196)	$ 168,935	$ 58,873	$ 30	(11)	$ 58,892

8. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2013	December 31, 2012
Accrued compensation	$ 1,375	$ 507
Accrued research and development expenses	4,756	3,280
Accrued professional fees	553	426
Other accrued expenses	248	297
Total	$ 6,932	$ 4,510

Accrued research and development expenses are comprised of amounts owed to third-party contract research organizations, clinical investigators, laboratories and data managers for research and development work performed on behalf of the Company.

9. Debt

Debt consists of the following:

	June 30, 2013	December 31, 2012
2011 Credit Facility, payable in monthly installments through March 2015, with fixed interest of 6.44% to 6.79% per annum	$ 525	$ 697
Total debt	525	697
Less: current portion	(361)	(350)
Total long-term debt, net of current portion	$ 164	$ 347

In March 2011, the Company entered into a Master Security Agreement for a $2,000 Capital Expenditure Line of Credit (the 2011 Credit Facility) with Webster Bank. Under the 2011 Credit Facility, the Company could draw down equipment loan advances for the purchase of new laboratory equipment through March 2013. The purchased laboratory equipment serves as collateral for the 2011 Credit Facility. The Company drew down a total of $1,047 under the 2011 Credit Facility.

The fair value for this debt would be classified as a level 2 measurement due to the use of inputs based on similar liabilities in the market. At this time, the carrying value approximates fair value.

10. Stock Based Compensation

The Company s 2006 Stock Incentive Plan, or the 2006 Plan, is administered by the Company s Board of Directors and provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights and other stock-based awards. The Company s officers, employees, consultants, advisors and directors are eligible to receive awards under the 2006 Plan; however, incentive stock options may only be granted to employees. Options granted are exercisable for a period determined by the Company, but in no event longer than ten years from the date of the grant. Options generally vest ratably over four years. There were 4,799 shares available to be granted under the 2006 Plan as of June 30, 2013.

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A summary of the status of the Company s stock option activity for the six months ended June 30, 2013 is presented in the table and narrative below:

	Options	Weighted Average Exercise Price
Outstanding at January 1, 2013	7,112	$ 5.56
Granted	910	7.59
Exercised	(100)	2.99
Forfeited	(20)	5.46
Cancelled		
Outstanding at June 30, 2013	7,902	$ 5.83
Options exercisable at June 30, 2013	4,067	$ 4.72
Weighted-average fair value of options granted during the period		$ 4.00

The Company utilizes the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of the stock-based awards. The assumptions used to value options granted are as follows:

	For the Six Months Ended	
	June 30, 2013	June 30, 2012
Expected term of option	5.0 - 6.1 years	5.0 - 6.1 years
Expected volatility	87 - 88%	88%
Risk free interest rate	1.01 - 1.69%	0.92 - 1.33%
Expected dividend yield	0%	0%

Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees was $2,978 and $1,602 for the six months ended June 30, 2013 and 2012, respectively. The Company recorded no tax benefit related to these options since the Company currently maintains a full valuation allowance on its deferred tax assets.

As of June 30, 2013, the intrinsic value of the options outstanding was $21,696, of which $16,425 related to vested options and $5,271 related to unvested options. The intrinsic value of stock options is calculated based on the difference between the exercise prices of the underlying common stock and the quoted stock price of the Company s common stock as of the reporting date.

As of June 30, 2013, the total compensation cost related to unvested options not yet recognized in the financial statements is approximately $16,008, net of estimated forfeitures, and the weighted average period over which this amount is expected to be recognized is 1.6 years.

11. Comprehensive Loss

The Company reports and presents comprehensive loss in accordance with ASC 220, *Comprehensive Income*, which establishes standards for reporting and display of comprehensive loss and its components in a full set of general purpose financial statements. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners (comprehensive loss). The Company s other comprehensive loss arises from net unrealized losses on marketable securities and was immaterial for all periods presented.

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12. Stockholders Equity

Changes in stockholders equity for the six months ended June 30, 2013 and 2012 were as follows:

	For the Six Months Ended June 30, 2013	2012
Balance at December 31, 2012 and 2011	$ 72,047	$ 70,968
Net loss	(31,678)	(20,668)
Stock based compensation	3,087	1,735
Exercise of stock options	298	1,237
Change in unrealized loss on marketable securities	(160)	32
Issuance of common stock	133,211	
Issuance of common stock under the Employee Stock Purchase Plan	105	88
Balance at June 30, 2013 and 2012	$ 176,910	$ 53,392

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

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, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we believe, expect, anticipate, plan, target, intend and similar expressions should be considered forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including factors discussed in this section and elsewhere in this quarterly report on Form 10-Q, including those discussed in Item 1A of this report under the heading Risk Factors, and the risks discussed in our other filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management s analysis, judgment, belief or expectation only as the date hereof. We assume no obligation to update these forward-looking statements to reflect events or circumstances that arise after the date hereof.

Overview

We are a biopharmaceutical company that was established to discover, develop and commercialize innovative treatments for infectious diseases. Within the anti-infective market, we are currently concentrating on the development of antivirals for the treatment of chronic hepatitis C viral infection, or HCV. We are currently focusing our efforts on developing the following four drug candidates which we intend to study in combination with each other and/or potentially in combination with compounds owned by others:

- Sovaprevir, a NS3 protease inhibitor being investigated for the treatment of HCV, currently in phase II clinical development;
- ACH-3102, a NS5A inhibitor being investigated for the treatment of HCV, currently in phase II clinical development;
- ACH-2684, a NS3 protease inhibitor being investigated for the treatment of HCV, which recently completed phase I clinical development.
- ACH-3422, a nucleotide NS5B polymerase inhibitor, currently being tested in investigational new drug, or IND, application-enabling preclinical studies.

We are currently conducting an international Phase II clinical trial with sovaprevir and ACH-3102 for the treatment of genotype 1 HCV. The trial will evaluate an all-oral 12-week interferon-free regimen consisting of sovaprevir, ACH-3102, and ribavirin in patients with chronic HCV who have not received prior therapy. We are also conducting IND-enabling preclinical studies for ACH-3422.

In June 2013, the U.S. Food and Drug Administration, or FDA, placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subject drug-drug interaction (DDI) study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. The FDA has allowed continued enrollment and treatment of patients in the phase II -007 clinical trial evaluating 12-weeks of sovaprevir in combination with ACH-3102 and ribavirin for patients with treatment-naive genotype 1 HCV. In order to resolve the clinical hold, the FDA has asked for study reports from two drug-drug interaction studies, an integrated safety analysis of on-going sovaprevir trials, and future development plans and protocols, each of which we expect to provide to the FDA in August 2013. For a further discussion of this clinical hold, see Financial Operations Overview Research and Development.

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In addition, we have established a pipeline of certain antibacterial product candidates for which we have or are seeking appropriate collaborative partners, but to which we are not devoting significant resources at this time. We have also developed and out licensed certain development and commercialization rights to elvucitabine, for the treatment of both Hepatitis B, or HBV, and human immunodeficiency virus, or HIV.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of $341 million from inception through June 30, 2013 and had an accumulated deficit of $354 million at June 30, 2013, which includes preferred stock dividends recognized until our initial public offering in 2006. Our net losses were $31.7 million and $20.7 million for the six months ended June 30, 2013 and 2012, respectively.

We have funded our operations primarily through proceeds from the sale of equity securities, including our initial public offering in October 2006, private placements of our common stock in August 2008 and August 2010 and registered offerings of our common stock in January 2010, June 2011, August 2012 and February 2013.

In February 2013, we issued 16,894,410 shares of our common stock in an underwritten public offering, including the underwriter s exercise of an over-allotment option. We received net proceeds of $133.2 million.

In August 2012, we issued 6,367,853 shares of our common stock in a registered direct offering with funds managed by QVT Financial LP. We received net proceeds of $41.7 million.

In June 2011, we issued 11,040,000 shares of our common stock in an underwritten public offering, including the underwriters exercise of an over-allotment option. We received net proceeds of $60.9 million.

In August 2010, we issued 19,775,101 shares of our common stock and warrants to purchase 6,921,286 shares of common stock in a private placement to institutional and other accredited investors. We received net proceeds of $49.9 million.

In January 2010, we issued 10,275,000 shares of our common stock in an underwritten public offering. In February 2010, we issued an additional 1,541,250 shares of common stock in connection with the underwriters exercise of an over-allotment option. We received net proceeds of $22.6 million.

We expect to incur substantial and increasing losses for at least the next several years as we seek to:

- continue clinical testing of sovaprevir, ACH-3102 and ACH-2684;
- continue IND-enabling preclinical studies and initiate clinical testing of ACH-3422; and
- identify and progress additional drug candidates.

We will need substantial additional financing to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities, which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available on terms favorable to us, if at all.

In addition to the risks associated with early-stage companies, there can be no assurance that we will successfully complete our research and development, obtain adequate patent protection for our technology, obtain necessary government regulatory approval for drug candidates we develop, find and maintain appropriate collaboration partners or that any approved drug candidates will be commercially viable. In addition, we may not be profitable even if we succeed in commercializing any of our drug candidates.

Financial Operations Overview

Revenue

To date, we have not generated revenue from the sale of any drugs. The majority of our revenue recognized to date has been derived from our former collaboration with Gilead to develop compounds for use in treating HCV, which was terminated in February 2012.

During the six months ended June 30, 2013 and 2012 we recognized $0 and $2.5 million, respectively, under this collaboration agreement. Revenue recognized during the six months ended June 30, 2012 consisted of recognition of the remaining deferred revenue related to this former collaboration, as effective with the termination of the collaboration we no longer had any future obligations under the collaboration.

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Research and Development

Our research and development expenses reflect costs incurred for our proprietary research and development projects. These costs consist primarily of salaries and benefits for our research and development personnel, costs of services by clinical research organizations, other outsourced research, materials used during research and development activities, facility-related costs such as rent and utilities associated with our laboratory and clinical development space and operating supplies.

Within the anti-infective market, we are concentrating on the development of antivirals for the treatment of HCV. Currently, we are developing our lead clinical-stage drug candidates for the treatment of HCV, including sovaprevir and ACH-3102, each currently in phase II clinical development, and ACH-2684, which recently completed a phase I clinical trial and ACH-3422, which is currently in IND-enabling preclinical studies. In the near term, we intend to focus our efforts on (i) completing clinical development of a combination regimen including sovaprevir and ACH-3102, with and without ribavirin, (ii) continuing non-therapeutic studies of sovaprevir and ACH-3102 (iii) continuing IND-enabling preclinical studies for ACH-3422 and (iv) exploring potential development of our drug candidates with other drug developers under cooperative or other study arrangements.

In addition, we have established a pipeline of certain antibacterial product candidates for which we have or are seeking appropriate collaborative partners, but to which we are not devoting significant resources at this time. We have also developed and out- licensed certain development and commercialization rights to elvucitabine, for the treatment of both Hepatitis B, or HBV, and human immunodeficiency virus, or HIV.

We have established our current HCV drug candidate pipeline entirely through our internal discovery capabilities. Through these efforts we have identified and are developing the following portfolio of drug candidates which we intend to study in combination with each other and/or potentially in combination with compounds owned by others:

Sovaprevir, **a NS3 Protease Inhibitor.** During the second quarter of 2013, we initiated a randomized, double-blind phase II clinical trial that will evaluate a 12 week treatment consisting of sovaprevir and our NS5A inhibitor, ACH-3102, with ribavirin for the treatment of genotype 1 HCV (the -007 trial) and we expect initial RVR data to be available in the third quarter of 2013 and SVR data to be available in the fourth quarter of 2013. In prior clinical trials, we completed a phase IIa clinical trial conducted in both the United States and Europe to assess sovaprevir s safety, tolerability, pharmacokinetic properties and efficacy when dosed with pegylated interferon and ribavirin (P/R) in treatment-naïve, genotype 1 HCV-infected subjects. In this trial, sovaprevir was demonstrated to achieve a complete early virologic response, or cEVR, after twelve weeks of dosing, in 94% to 100% of patients. Mean viral load, a measurement of the amount of virus in the blood stream, was reduced in HCV-infected patients by 4.56 log10 to 5.08 log10, or reduction of over 99.9% of the virus. Sovaprevir continued to be safe and well-tolerated with no significant drug-related adverse events. Liver enzyme elevations were observed with higher doses of sovaprevir, were transient, and returned to baseline while on treatment. In addition, sustained virologic response twelve weeks (SVR12) after the completion of therapy was achieved in 77% to 85% of patients after completion of 24 weeks of therapy (12 weeks of sovaprevir plus P/R, followed by 12 weeks of P/R). Mutations commonly associated with protease inhibitor therapy including mutations at R155, A156 and D168 were not observed with sovaprevir treatment. Sovaprevir has been granted Fast Track status by the United States Food and Drug Administration, or FDA.

In June 2013, we received notice from the FDA that a clinical hold has been placed on sovaprevir after elevations in liver enzymes were noted in a Phase 1 healthy subject DDI study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. The FDA has allowed continued enrollment and treatment of patients in the phase II -007 clinical trial evaluating 12-weeks of sovaprevir in combination with ACH-3102 and ribavirin for patients with treatment-naive genotype 1 HCV. In a Phase 1 drug-drug interaction study, we were evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. While conducting this study, we detected unanticipated elevations in ALT liver enzymes (grade 3 or 4) in multiple subjects, although none of these met the criteria for a serious adverse event (SAE). We voluntarily stopped further dosing in the DDI study and promptly notified the FDA of these findings. Preliminary pharmacokinetic results indicate a metabolic interaction whereby plasma concentrations of sovaprevir were substantially increased upon co-administration. Such ALT elevations have not been seen in the 12-week combination -007 trial, the 12-week combination -005 trial with ACH-3102 and ribavirin, or in any other drug-drug interaction studies completed with sovaprevir to date. With the preliminary draft data on hand at the time of notification, the FDA placed sovaprevir on clinical hold. In order to resolve the clinical hold, the FDA has asked for study reports from two drug-drug interaction studies, an integrated safety analysis of on-going sovaprevir trials, and future development plans and protocols, each of which we expect to provide to the FDA in August 2013.

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ACH-3102, a NS5A Inhibitor. We have completed a proof-of-concept clinical trial of our second-generation, pan-genotypic NS5A inhibitor, ACH-3102, and we are currently studying the drug candidate in a blinded study in combination with sovaprevir, our protease inhibitor, and ribavirin. This trial was initiated in the second quarter of 2013 and we expect initial RVR data to be available in the third quarter of 2013. In phase Ia safety and pharmacokinetic studies, more than 70 healthy volunteers received either a single ascending dose of ACH-3102, or 14 days of once-daily ACH-3102. Data from both the single and multiple ascending dose groups demonstrated that ACH-3102 was well tolerated with no serious adverse events. In phase Ib, ACH-3102 demonstrated proof-of-concept efficacy results after a single dose of ACH-3102 in patients with genotype 1a HCV. In all, 12 patients were treated with a single dose of either 50 mg, 150 mg, or 300 mg of ACH-3102, with a mean maximum decline in HCV RNA of 3.78, 3.52, and 3.93 log10 achieved, respectively. In phase II, we studied ACH-3102 in an open-label phase IIa pilot trial evaluating 12-weeks of once-daily ACH-3102 in combination with ribavirin for the treatment of HCV genotype 1b. Results from that trial revealed that 75% of patients (6 of 8) who had completed 4 weeks of therapy achieved rapid virologic response, or RVR, meaning undetectable levels of virus at 4 weeks of therapy, and 75% of patients (6 of 8) achieved undetectable levels of virus at end of treatment, or ETR. Further, 63% of patients (5 of 8) receiving 12 weeks of therapy demonstrated undetectable levels of HCV 4 weeks after cessation of therapy, or SVR4. We expect that final data will be available at a future medical meeting. ACH-3102 has been granted Fast Track status by the FDA.

ACH-2684, a NS3 Protease Inhibitor. ACH-2684 has most recently completed phase Ib proof-of-concept clinical studies, including three segments: once-daily dosing in genotype 1, twice-daily dosing in patients with genotype 3 and once-daily dosing in patients with cirrhosis. Once-daily doses of 400mg of ACH-2684 reduced viral load by a mean maximum 3.73 log10 in patients with HCV genotype 1. In addition, twice daily doses of 400mg of ACH-2684 reduced viral load by a maximal 2.03 log10 in patients with HCV genotype 3. Lastly, once-daily doses of 400mg administered for three days to HCV patients with cirrhosis achieved a mean maximum 3.67 log10 reduction in HCV viral load, similar to the antiviral activity achieved in non-cirrhotic genotype 1 HCV patients receiving the same dose of ACH-2684. ACH-2684 demonstrated good safety and tolerability in these phase Ib clinical studies, as well as in phase Ia studies in healthy volunteers. Our current strategic plan includes the combination development of ACH-2684 with ACH-3102 in a 12-week combination clinical study. We also remain interested in combining ACH-2684 with other compounds under cooperative study arrangements.

ACH-3422, a NS5B Nucleotide Polymerase Inhibitor. ACH-3422 is a small molecule, nucleotide prodrug inhibitor of HCV NS5B polymerase. In vitro, ACH-3422 has demonstrated excellent potency, with activity demonstrated across all genotypes of HCV and an EC50 of approximately 50 to 65 nanomolar against genotype 1 HCV. To date, we have completed 14-day safety studies in animals, where no significant findings were noted at the highest dose tested. ACH-3422 appears to have high oral bioavailability, rapid uptake and conversion of the prodrug into the monophosphate within the liver, and a pharmacokinetic profile supportive of once-daily dosing. We have initiated manufacturing and IND-enabling preclinical studies for ACH-3422 and plan to file an IND with the FDA in the first quarter of 2014.

We intend to continue to focus on the discovery and development of new drug candidates through our extensive expertise in virology, microbiology and synthetic chemistry. Although significant additional funding and research and development will be required to support these efforts, we believe our drug discovery capabilities will allow us to further expand our product candidate portfolio, providing us with strong growth potential and, over time, reducing our reliance on the success of any single drug candidate.

All costs associated with internal research and development, and research and development services for which we have externally contracted, are expensed as incurred. The costs of obtaining patents for our drug candidates are expensed as incurred as indirect costs.

	Six Months Ended June 30,	
	2013	2012
	(in thousands)	
Clinical candidate direct external costs:		
Sovaprevir (and related compounds)	$ 4,503	$ 4,846
ACH-3102 (and related compounds)	4,861	4,339
Sovaprevir/ACH-3102 combination trials	7,431	
ACH-2684 (and related compounds)	629	1,417
ACH-3422 (and related compounds)	223	
ACH-2928 (and related compounds)	4	522
Other	270	570

	17,921	11,694
Direct internal personnel costs	5,620	4,723
Sub-total direct costs	23,541	16,417
Indirect costs and overhead	1,837	1,607
Research and development tax credit	(90)	(103)
Total research and development	$ 25,288	$ 17,921

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We are currently conducting phase II clinical trials of sovaprevir and ACH-3102, as well as IND-enabling preclinical studies of ACH-3422.

The State of Connecticut provides companies with the opportunity to exchange certain research and development credit carryforwards for cash in exchange for foregoing the carryforward of the research and development credit. The program provides for such exchange of the research and development credits at a rate of 65% of the annual research and development credit, as defined. This benefit is recorded as a reduction of research and development expenditures.

We expect research and development expenses associated with the completion of these programs to be substantial and to increase over time. We do not believe, however, that it is possible at this time to know or accurately project the nature, timing or total amount of program-specific expenses through commercialization. There exist numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will evolve and therefore impact our clinical development programs and plans over time.

General and Administrative

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses for general and administrative personnel.

Critical Accounting Standards and Estimates

Preparation of our financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. A summary of our critical accounting estimates is included in Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2012. We continually review these estimates and their underlying assumptions to ensure they are appropriate for the circumstances. Changes in the estimates and assumptions we use could have a significant impact on our financial results. During the first six months of 2013, there were no significant changes in our estimates and critical accounting policies.

Results of Operations

Preparation of our financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. A summary of our critical accounting estimates is included in Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2012. We continually review these estimates and their underlying assumptions to ensure they are appropriate for the circumstances. Changes in the estimates and assumptions we use could have a significant impact on our financial results. During the first six months of 2013, there were no significant changes in our estimates and critical accounting policies.

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

Revenue. We recognized no revenue for the three months ended June 30, 2013 or 2012, and $0 and $2.5 million for the six months ended June 30, 2013 and 2012, respectively. Revenue recognized during the six months ended June 30, 2012 consisted of amounts derived from our former collaboration with Gilead. During this period, effective with the termination of the collaboration, we recognized the remaining $2.5 million of deferred revenue as we no longer had any future obligations under the collaboration.

Research and Development Expenses. Research and development expenses were $16.6 million and $9.0 million for the three months ended June 30, 2013 and 2012, respectively, and $25.3 million and $17.9 million for the six months ended June 30, 2013 and 2012, respectively. The increase for the three and six months ended June 30, 2013 was primarily due to increased costs related to combination clinical trials and drug interaction studies of sovaprevir and ACH-3102 as well as increased consulting fees. Personnel costs and non-cash charges related to stock based compensation also increased primarily due to the addition of personnel in our development group. These amounts were partially offset by decreased clinical trial expenses related to ACH-2684 and ACH-2928. We expect research and development expenses to increase moderately during the remainder of the year, as we continue clinical testing of sovaprevir and ACH-3102 and complete IND-enabling studies of ACH-3422. Research and development expenses for the three and six months ended June 30, 2013 and 2012 are comprised as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	Change	% Change	2013	2012	Change	% Change
Personnel costs	$ 2,300	$ 2,160	$ 140	6%	$ 4,580	$ 4,105	$ 475	12%
Stock based compensation	481	233	248	106%	1,040	618	422	68%
Outsourced research and supplies	12,488	5,636	6,852	122%	17,148	11,071	6,077	55%
Professional and consulting fees	707	382	325	85%	1,405	1,093	312	29%
Facilities costs	484	513	(29)	(6%)	1,007	1,005	2	
Travel and other costs	153	88	65	74%	198	132	66	50%
Research and development tax credit	(45)	(33)	(12)	36%	(90)	(103)	13	(13%)
Total	$ 16,568	$ 8,979	$ 7,589	85%	$ 25,288	$ 17,921	7,367	41%

General and Administrative Expenses. General and administrative expenses were $3.5 million and $2.6 million for the three months ended June 30, 2013 and 2012, respectively, and $6.6 million and $5.3 million for the six months ended June 30, 2013 and 2012, respectively. The increase for the three and six months ended June 30, 2013 was primarily due to an increase in non-cash charges related to stock based compensation as a result of option grants made at 2012 year end. We expect that general and administrative expenses will be consistent for the remainder of the year. General and administrative expenses for the three and six months ended June 30, 2013 and 2012 are comprised as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2013	2012	Change	% Change	2013	2012	Change	% Change
Personnel costs	$ 908	$ 708	$ 200	28%	$ 1,808	$ 1,549	$ 259	17%
Stock based compensation	1,183	582	601	103%	2,047	1,117	930	83%
Professional and consulting fees	847	762	85	11%	1,592	1,635	(43)	(3%)
Facilities costs	277	279	(2)	(1%)	562	494	68	14%
Travel and other costs	330	249	81	33%	610	523	87	17%
Total	$ 3,545	$ 2,580	$ 965	37%	$ 6,619	$ 5,318	$ 1,301	24%

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Other Income (Expense). Interest income was $185,000 and $55,000 for the three months ended June 30, 2013 and 2012, respectively. The $130,000 or 236% increase was primarily due to increased average cash balances in 2013. Interest expense was $12,000 and $23,000 for the three months ended June 30, 2013 and 2012, respectively. The $11,000 or 48% decrease was primarily due to lower average debt facility balances outstanding in 2013.

Interest income was $263,000 and $119,000 for the six months ended June 30, 2013 and 2012, respectively. The $144,000 or 121% increase was primarily due to increased average cash balances in 2013. Interest expense was $34,000 and $37,000 for the six months ended June 30, 2013 and 2012, respectively. The $3,000 or 8% decrease was primarily due to higher average debt facility balances outstanding in 2012.

Liquidity and Capital Resources

Since our inception in August 1998, we have financed our operations primarily through proceeds from the sale of equity securities. Through June 30, 2013, we have received approximately $515.9 million in aggregate gross proceeds from stock issuances, including convertible preferred stock, our initial public offering in 2006, private placements of our common stock in 2008 and 2010 and registered offerings of our common stock in 2010, 2011, 2012 and 2013.

As of June 30, 2013, our debt balance due to borrowings was $525,000 with a weighted average interest rate of 6.54%.

We had $186.1 million and $77.4 million in cash, cash equivalents and marketable securities as of June 30, 2013 and December 31, 2012, respectively. We regularly review our investments and monitor the financial markets. As of June 30, 2013, our cash, cash equivalents and marketable securities consisted of high-quality financial instruments, primarily money market funds, government sponsored bond obligations and other corporate debt securities which we believe are subject to limited credit risk.

Cash used in operating activities was $26.4 million for the six months ended June 30, 2013 and was primarily attributable to our $31.7 million net loss combined with $3.1 million in premiums paid on the purchase of marketable securities, primarily offset by non-cash stock based compensation and increases in accounts payable and accrued expenses. Cash used in operating activities was $21.2 million for the six months ended June 30, 2012 and was primarily attributable to our $20.7 million net loss combined with a decrease in deferred revenue and an increase in prepaid expenses. This was partially offset by non-cash stock based compensation, combined with an increase in accrued expenses.

Cash used in investing activities was $108.3 million for the six months ended June 30, 2013 and was primarily attributable $144.9 million in purchases of marketable securities, partially offset by maturities of marketable securities. Cash provided by investing activities was $21.5 million for the six months ended June 30, 2012 and was primarily attributable to the maturities of marketable securities offset by purchases of marketable securities.

Cash provided by financing activities was $133.4 million for the six months ended June 30, 2013 and was primarily attributable to $133.2 million in net proceeds from our public offering in February 2013. Cash provided by financing activities was $1.8 million for the six months ended June 30, 2012 and was primarily attributable to proceeds from the exercise of stock options combined with borrowings from our credit facility.

We expect to incur continuing and increasing losses from operations for at least the next several years as we seek to:

- continue clinical testing of sovaprevir, ACH-3102, and ACH-2684;
- continue IND-enabling preclinical studies and initiate clinical testing of ACH-3422; and
- identify and progress additional drug candidates.

We do not expect our existing capital resources, together with any milestone payments and research and development funding we may receive, to be sufficient to fund the completion of the development of any of our drug candidates. As a result, we will need to raise additional funds prior to, among other things, being able to market any drug candidates, to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities. We will seek to raise such additional financing through (i) public or private equity or debt financings, (ii) collaborative or other arrangements with third parties or (iii) other sources of financing.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our projected operating requirements through at least June 30, 2014. However, our funding resources and requirements may change and will depend upon numerous factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of sovaprevir, ACH-3102, ACH-2684, and ACH-3422, including additional studies, if any, that may be required to resolve the clinical hold on sovaprevir;

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- the scope of and costs associated with entering cooperative study arrangements, or CSAs, if any, for the collaborative development of our drug candidates in combination with other s drug candidates;
- the costs involved in obtaining regulatory approvals for our drug candidates;
- the scope, prioritization and number of programs we pursue;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- our ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact our ability to obtain capital in the future;
- our acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to us.

We intend to augment our cash balance through financing transactions, including the issuance of debt or equity securities, and/or further corporate alliances. There can be no assurance that we will be able to obtain adequate levels of additional funding or favorable terms, if at all. If adequate funds are not available, we will be required to:

- delay, reduce the scope of or eliminate research and development programs;
- obtain funds through arrangements with collaborators or others on terms unfavorable to us or that may require us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently; and/or
- pursue merger or acquisition strategies.

If our operating plan changes, we may need additional funds sooner than planned. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay preclinical studies, clinical trials or other development activities for one or more of our drug candidates. We may seek additional financing through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest will be diluted, and the terms may include adverse liquidation or other preferences that adversely affect stockholders rights.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Recently Issued Accounting Standards

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. This standard requires additional disclosures regarding the reporting of reclassifications out of accumulated other comprehensive income (AOCI). This ASU is effective for reporting periods beginning after December 15, 2012. We evaluated this pronouncement effective January 1, 2013 and determined the further breakout of accumulated other comprehensive income is immaterial to our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. Our exposure to market risk is confined to our cash, cash equivalents and marketable securities. We regularly review our investments and monitor the financial markets. We invest in high-quality financial instruments, primarily money market funds, government sponsored bond obligations and government-backed corporate debt securities, with the effective duration of the portfolio less than twelve months and no security with an effective duration in excess of twenty four months, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We do not believe that we have any material exposure to interest rate risk or changes in credit ratings arising from our investments.

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Capital Market Risk. We currently have no product revenues and depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2013. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2013, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective, at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a 15(d) and 15d 15(d) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. These risk factors restate and supersede in their entirety the risk factors previously disclosed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2012.

Risks Related to Our Business

We depend on the success of our HCV drug candidates, which are still under development.

We have invested a significant portion of our efforts and financial resources in the development of our candidates for the treatment of HCV, including our protease inhibitors, sovaprevir and ACH-2684, our NS5A inhibitor, ACH-3102 and our nucleotide polymerase inhibitor, ACH-3422. Our ability to generate revenues will depend heavily on the successful development and commercialization of these drug candidates. The development and commercial success of these drug candidates will depend on several factors, including the following:

- our ability to provide acceptable evidence of the safety and efficacy of these drug candidates in current and future clinical trials;
- our ability to provide acceptable evidence of the ability of our drug candidates to be dosed safely in combination with other drugs and/or drug candidates, both ours and others;
- our ability to favorably resolve the FDA s clinical hold on sovaprevir;

our ability to develop drug formulations that will deliver the appropriate drug exposures in longer term clinical trials;

our ability to obtain patent protection for our drug candidates and freedom to operate under third party intellectual property;

receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

establishing commercial manufacturing arrangements with third-party manufacturers;

launching commercial sales of successfully developed drugs, whether alone or in collaboration with others;

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acceptance of drugs in the medical community and with third-party payors; and

our ability to identify, enter into and maintain collaboration arrangements with appropriate strategic partners for our drug candidates.

Positive results in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the preclinical studies or completed clinical trials for sovaprevir, ACH-3102, ACH-2684 or ACH-3422 may not be predictive of the results we may obtain in later stage trials.

We do not expect any of our drug candidates for the treatment of HCV to be commercially available for at least several years, if at all.

The U.S. FDA has placed sovaprevir on clinical hold after elevations in liver enzymes were noted in a Phase 1 healthy subject drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. Our business may be adversely affected if the clincal hold cannot be timely resolved or if such regulatory concerns lead to more burdensome preclinical or clinical studies that cause significant delays in developing our drug candidates.

On June 28, 2013, the FDA placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subject drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. The FDA has allowed continued enrollment and treatment of patients in the phase II -007 clinical trial evaluating 12-weeks of sovaprevir in combination with ACH-3102 and ribavirin for patients with treatment-naive genotype 1 hepatitis C viral infection. In order to resolve the clinical hold, the FDA has asked for study reports from two drug-drug interaction studies, an integrated safety analysis of on-going sovaprevir trials, and future development plans and protocols, each of which we expect to provide to the FDA in the next several weeks. We cannot assure you that the FDA will lift the clinical hold and allow us to pursue further development of sovaprevir. If the FDA, upon receipt of these reports, fails to lift the clinical hold, or determines that we must discontinue enrollment and treatment of patients in the ongoing -007 clinical trial, our development timelines and our business would be adversely affected and our stock price would likely decline. Further, even if the FDA lifts the clinical hold, or if the FDA or other regulatory agencies continue to express safety concerns even after the hold is lifted, future preclinical or clinical studies involving sovaprevir or combination regimens which include sovaprevir, may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. In such instance, our progress in the development of these drug candidates may be significantly slowed and the associated costs may be significantly increased, adversely affecting our business.

Our market is subject to intense competition. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.

We are engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target infectious diseases generally and HCV in particular. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of HCV. Additionally, there may be competitive drugs currently under development of which we are not aware.

If approved, our protease inhibitors, sovaprevir and ACH-2684, and our NS5A inhibitor, ACH-3102, and our nucleotide polymerase inhibitor, ACH-3422, would compete with drugs currently approved for the treatment of HCV, i.e., the interferon-alpha-based products from Roche (Pegasys and Roferon-A) or Merck (Intron-A or Peg-Intron), the ribavirin-based products from Merck (Rebetrol), Roche (Copegus) and generic versions sold by various companies, as well as recently-approved protease inhibitors telaprevir by Vertex (Incivek) and boceprevir by Merck (Victrelis).

If approved, our drug candidates may also compete with all-oral treatments currently in development to treat HCV infection in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside, nucleotide, and non-nucleoside), NS5A inhibitors and cyclophilin inhibitors. Competing drug candidates for the treatment of HCV, or combinations of drug candidates, are being developed by companies such as Abbvie, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Enanta, Gilead, GlaxoSmithKline, Idenix, Johnson & Johnson, Presidio, Medivir, Merck, Novartis, Pfizer, Roche, Valeant and Vertex.

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Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;
- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- drug candidates that have been approved or are in late-stage clinical development; and/or
- collaborative arrangements in our target markets with leading companies and research institutions.

Competitive products, specific classes of competitive products, or combinations of competitive products, may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for any of our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenues, we will not be profitable.

We have incurred significant losses since our inception in August 1998. As of June 30, 2013, our accumulated deficit was approximately $354 million. We have not generated any revenue from the sale of drug candidates to date. We expect that our annual operating losses will increase over the next several years as we expand our research, development and commercialization efforts.

To become profitable, we must successfully develop and obtain regulatory approval for our drug candidates and effectively manufacture, market and sell any drug candidates we develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

We will need substantial additional capital to fund our operations, including drug candidate development, manufacturing and commercialization. If we do not have or cannot raise additional capital when needed, we will be unable to develop and commercialize our drug candidates successfully, and our ability to operate as a going concern may be adversely affected.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to support our current operating plan through at least June 30, 2014. Our operating plan may change as a result of many factors, including:

- the costs involved in the clinical development, manufacturing and formulation of our protease inhibitors, sovaprevir and ACH-2684, our NS5A inhibitor, ACH-3102, and our nucleotide polymerase inhibitor, ACH-3422, including additional studies, if any, that may be required to resolve the clinical hold on sovaprevir;
- the scope of and costs associated with entering cooperative study arrangements, or CSAs, if any, for the collaborative development of our drug candidates in combination with others drug candidates;

the costs involved in obtaining regulatory approvals for our drug candidates;

the scope, prioritization and number of programs we pursue;

the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;

our ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact our ability to obtain capital in the future;

our acquisition and development of new technologies and drug candidates; and

competing technological, regulatory and market developments currently unknown to us.

If our operating plan changes, we may need additional funds sooner than planned. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional

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capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay preclinical studies, clinical trials or other development activities for one or more of our drug candidates. We may seek additional financing through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. For example, in November 2012 we entered into an agreement with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell up to $50,000,000 of shares of our common stock at the market through Cantor pursuant to a universal shelf registration statement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest will be diluted, and the terms may include adverse liquidation or other preferences that adversely affect stockholders rights. Since August 2008, we have issued an aggregate of 76,608,269 shares of our common stock in two private placements and four registered offerings as well as warrants to purchase an aggregate of 13,279,028 shares of our common stock. As of June 30, 2013, we have 5,347,796 warrants outstanding. These financings substantially diluted our existing stockholders.

Stockholders will be further diluted if, and to the extent, any warrants are exercised. Debt financing, if available, may involve covenants that limit or restrict our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends, or may involve immediate repayment of the debt under certain circumstances. If we raise additional funds through collaborations, strategic alliances and licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us.

If we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction.

If appropriate opportunities become available, we may license or acquire technologies, resources, drugs or drug candidates. We may never realize the anticipated benefits of such a transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the drug candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, the creation of contingent liabilities, material impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

If we are not able to attract and retain key management, scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.

We depend upon our senior management and scientific staff for our business success, particularly Dr. Milind Deshpande, our president and chief executive officer. All of our employment agreements with our senior management employees are terminable without notice by the employee. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of drug development and other business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would adversely affect our business.

If biopharmaceutical companies involved in HCV drug development continue to consolidate, competition may increase and our business may be harmed.

In late 2011 and early 2012, several acquisitions of smaller biopharmaceutical companies by larger biopharmaceutical companies took place at substantial premiums over the market capitalizations of the target companies, including the acquisitions of Anadys Pharmaceuticals, Pharmasset, Inc. and Inhibitex Pharmaceuticals, by Roche, Gilead and Bristol-Myers Squibb, respectively. If such consolidation continues to take place, we may face competitive pressures to a far greater degree than had those consolidations not occurred, resulting from the greater resources the larger pharmaceutical companies can put toward their development pipelines. Further, if investors who provide capital to our industry continue to seek and advocate for similar acquisitions at similar premiums, we may not be able to satisfy their higher expectations for market value appreciation and our stock price may decline.

Our business has a substantial risk of product liability claims. If we are unable to obtain or maintain appropriate levels of insurance, a product liability claim could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. Product liability claims could delay or prevent completion of our clinical development programs. We currently have clinical trial insurance in an

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amount equal to up to $20.0 million in the aggregate and will seek to obtain product liability insurance prior to the sales and marketing of any of our drug candidates. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a successful claim. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include revenue recognition, stock-based compensation expense, accrued expenses and deferred tax assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Standards and Estimates elsewhere in this Quarterly Report on Form 10-Q.

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liabilities and the further development of our product candidates may be delayed.

Risks Related to the Development of Our Drug Candidates

All of our drug candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval. If we are unable to successfully develop, test and commercialize our drug candidates, we will not be successful.

To date, we have not commercially marketed, distributed or sold any drug candidates. The success of our business depends primarily upon our ability to develop and commercialize our drug candidates successfully. Our drug candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy testing and obtain regulatory approval of our drug candidates. Despite our efforts, our drug candidates may not:

- offer therapeutic or other improvement over existing, comparable drugs;
- be proven safe and effective in clinical trials;
- have the desired effects, or may include undesirable effects or may have other unexpected characteristics;
- meet applicable regulatory standards;

be capable of being produced in commercial quantities at acceptable costs; or

be successfully commercialized.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

regulators or Institutional Review Boards, or IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

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- our preclinical tests or clinical trials for our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising;

- enrollment in our clinical trials may be slower than we currently anticipate as potential participants have access to commercially launched DAAs, telaprevir (Incivek) or boceprevir (Victrelis), as well as other experimental therapies under development, or participants may not remain adherent to our clinical trial protocols or may drop out of our clinical trials at a higher rate than we currently anticipate, each resulting in significant delays;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

- we might have to suspend or terminate our clinical trials if the participants in our trials, or in third-party trials of similar HCV drug candidates, are exposed to unacceptable health risks;

- IRBs or regulators, including the FDA, may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

- the FDA may require us to carry out more extensive studies, evaluate different treatment combinations or complete comparative effectiveness studies, resulting in significant delays and/or increased costs; and

- the supply or quality of our drug candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate.

In addition, the current standard of care for the treatment of HCV is telaprevir (Incivek) or boceprivir (Victrelis) in combination with P/R. If the current standard of care changes, for example due to the approval by the FDA of new classes of compounds that provide better safety or efficacy, then we could be required to carry out more extensive studies, evaluate different treatment combinations or complete comparative effectiveness studies, resulting in significant delays and/or increased costs.

We, and a number of other companies in the pharmaceutical and biotechnology industries, have suffered significant setbacks in later stage clinical trials even after achieving promising results in early-stage development.

Expenses associated with clinical trials may cause our earnings to fluctuate, which could adversely affect our stock price.

The clinical trials required for regulatory approval of our products, as well as clinical trials we are required to conduct after approval, are very expensive. It is difficult to accurately predict or control the amount or timing of these expenses from quarter to quarter, and the FDA and/or other regulatory agencies may require more clinical testing than we originally anticipated for our drug candidates. Uneven and unexpected spending on these programs may cause our operating results to fluctuate from quarter to quarter, and our stock price may decline.

If we are unable to obtain U.S. and/or foreign regulatory approval, we will be unable to commercialize our drug candidates.

Our drug candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, record keeping, labeling, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing will obtain marketing approval. In connection with the clinical trials for sovaprevir, ACH-3102, ACH-2684, ACH-3422, and any other drug candidate we may seek to develop in the future, we face risks that:

the drug candidate may not prove to be efficacious;

the drug candidate may not prove to be safe;

the results may not confirm the positive results from earlier preclinical studies or clinical trials;

the results may not meet the level of statistical significance required by the FDA or other regulatory agencies; and

the FDA or other regulatory agencies may require us to carry out additional studies.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for the FDA and other countries regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical

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activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to progress the development of a drug candidate and to generate revenues from that drug candidate. For example, in June 2013, the FDA placed a clinical hold on sovaprevir and we do not know whether or when the FDA will lift such clinical hold. Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product and affect reimbursement by third-party payors. These limitations may limit the size of the market for the product. We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

If clinical trials for our drug candidates are prolonged or delayed, we may be unable to commercialize our drug candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend or terminate clinical trials, or delay the analysis of data from our completed or ongoing clinical trials.

Further, we cannot predict whether or how program discontinuations by competitors (such as the discontinuation in 2012 by Bristol-Myers Squibb of BMS-986094, a nucleotide polymerase inhibitor, due to serious cardiac-related adverse events) may increase the level of scrutiny by the FDA on our drug candidates, slowing data review and response times or otherwise creating delays or difficulties in initiating and progressing clinical trials. Any of the following could delay the clinical development of our drug candidates:

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling volunteers and patients into clinical trials;
- a lower than anticipated retention rate of volunteers and patients in clinical trials;
- delays in gathering and interpreting clinical data;
- the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;
- the requirement by the FDA, in connection with future HCV development guidelines recently circulated for comment, to carry out additional studies;
- delays in completing formulation development of our drug candidates, or delays in planning and executing the bridging studies required to use the new formulations in subsequent clinical trials;

- inadequate supply or deficient quality of drug candidate materials or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or in third-party clinical trials of similar HCV drug candidates; or
- the placement by the FDA of a clinical hold on a trial.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the existence of clinical trials for competing drugs also in clinical development, the proximity of patients to clinical sites, the availability of effective treatments for the

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relevant disease and the eligibility criteria for the clinical trial. Delays in patient enrollment may result in increased costs and longer development times. We currently face competition for subjects to enroll in our clinical trials and may have to expand the number of sites at which the trials are conducted. If we are not successful in doing so, the planned timing for release of data from these trials may not be achieved. In addition, subjects may drop out of our clinical trials, and thereby impair the validity or statistical significance of the trials.

We, the FDA or other applicable regulatory authorities may suspend clinical trials of a drug candidate at any time if we or they believe the subjects or patients participating in such clinical trials are being exposed to unacceptable health risks or for other reasons. For example, on June 28, 2013, the FDA placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subject drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. We are currently in the process of seeking to resolve the hold. However, if the FDA fails to lift the hold or continues to express safety concerns our business and development timelines may be adversely affected. Additionally, when we advanced sovaprevir into longer term clinical trials in phase II, we established predetermined stopping rules, as well as a Data Safety Monitoring Board (DSMB) in order to monitor and ensure patient safety. Any interruption of these clinical trials, whether as a result of one of our drug candidates, or of co-administration of a concomitant anti-HCV agent, or of administrative review delays on the part of the DSMB or FDA, could cause delays in our drug development.

We cannot predict whether any of our drug candidates will encounter problems during clinical trials which will cause us or regulatory authorities to delay or suspend these trials, or which will delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates.

In addition, we, along with our collaborators or subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy. Employment of such a debarred person (even if inadvertently) may result in delays in the FDA s review or approval of our products, or the rejection of data developed with the involvement of such persons.

Fast Track designation does not guarantee approval, or expedited approval, of sovaprevir or ACH-3102 and there is no guarantee that sovaprevir or ACH-3102 will maintain Fast Track designation.

In December 2011 and May 2012, we announced that the FDA granted Fast Track designation to sovaprevir and ACH-3102, respectively, for the treatment of HCV. Under the FDA Modernization Act of 1997, Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions. Compounds selected must demonstrate the potential to address an unmet medical need for such a condition. Mechanisms intended to facilitate development include opportunities for frequent dialogue with FDA reviewers and for timely review of submitted protocols. However, the designation does not guarantee approval or expedited approval of any application for the product. Furthermore, the FDA may revoke Fast Track designation from a product candidate at any time if it determines that the criteria are no longer met.

Even if we obtain regulatory approvals, our drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals, and our business would be seriously harmed.

Even if we receive regulatory approval of any drugs we are developing or may develop, we will be subject to continuing regulatory review, including the review of clinical results which are reported after our drug candidates become commercially available approved drugs. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials. In addition, the manufacturer, and the manufacturing facilities we use to make any approved drugs, will also be subject to periodic review and inspection by the FDA.

The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions. Our product promotion and advertising is also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our marketed products will be limited by the terms and conditions of the FDA-approved labeling. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial

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publication or dissemination. If the FDA believes these materials or statements promote our products for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety-related information, the FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue a warning letter, which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs or biologics for unapproved uses, based on the False Claims Act and other federal laws governing reimbursement for such products under the Medicare, Medicaid and other federally supported healthcare programs. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and exclusion from federal healthcare programs.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development efforts involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposing of these materials comply with the standards prescribed by federal, state and local laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials.

Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Although we maintain workers compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. In addition, though we have environmental liability insurance, such coverage may not provide for all related losses. We may incur substantial costs to comply with, and substantial fines or penalties, if we violate any of these laws or regulations.

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with good clinical practices, or GCPs, and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under European Union, or E.U., regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the E.U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure, or (iv) national authorization procedures.

The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E.U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from biotechnology processes, such as genetic engineering or (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases.

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain applications.

The Federal Food, Drug and Cosmetic Act, or FDCA, provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new

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chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Risks Related to Our Dependence on Third Parties

We may not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our drug candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business may not succeed.

We may consider forming exclusive or non-exclusive alliances with major biotechnology or pharmaceutical companies to jointly develop, and commercialize if approved, our protease inhibitor candidates and/or our NS5A inhibitor candidates. In such alliances, we would expect our biotechnology or pharmaceutical collaborators to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales. We may not be successful in entering into any such alliances on favorable terms or in a timely manner, if at all. There are a limited number of collaboration partners whose pipeline of HCV clinical candidates are suitable for co-development with ours. There are also a limited number of potential collaboration partners without a robust HCV drug candidate pipeline, but demonstrated commercial interest in HCV therapeutics who may have interest in gaining rights to our HCV drug candidates. Recent consolidation may have reduced the number of potential partners further, making achieving a suitable partnership more difficult, potentially limiting our ability to command a significant premium in any such transaction. Further, if potential collaboration partners enter alliances with other competing HCV companies, our future business prospects may be harmed, as these alliances could reduce the pool of potential partners for our compounds and/or limit the value of such alliance.

Even if we do succeed in securing such alliances, we may not be able to maintain them if development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. For example, a 2004 license and collaboration agreement between us and Gilead for the advancement of certain HCV compounds operating by the mechanism of action known as NS4A antagonism was terminated in February 2012 as neither party was devoting significant time to advancing the compounds under the agreement. Furthermore, any delay in entering into collaboration agreements could delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market. Any such delay related to our collaborations could adversely affect our business.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not have the ability to independently conduct clinical trials for our drug candidates, and we rely on third parties such as contract research organizations, medical institutions and clinical investigators to enroll qualified patients and conduct our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. These third-party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our trial design. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

We currently depend on third-party manufacturers to produce our preclinical and clinical drug supplies and intend to rely upon third-party manufacturers to produce commercial supplies of any approved drug candidates. We also depend on third parties to assist us in developing appropriate formulations of our drug candidates. If, in the future, we manufacture any of our drug candidates, we will be required to incur significant costs and devote significant efforts to establish and maintain these capabilities.

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We rely upon third parties to produce material for preclinical and clinical testing purposes and intend to continue to do so in the future. We also depend on third parties to assist us in developing appropriate formulations of our drug candidates. We also expect to rely upon third parties to produce materials required for the commercial production of our drug candidates if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our drug candidates or market them. Further, if third parties are not successful in formulation development of our drug candidates, our development timelines may be delayed. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our drug candidates be manufactured according to current good manufacturing practice regulations. Any failure by us or our third-party manufacturers to comply with current good manufacturing practices and/or our failure to scale up our manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval of any of our drug candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action.

To date, our third-party formulators and manufacturers have met our formulation and manufacturing requirements, but we cannot be assured that they will continue to do so. Any performance failure on the part of our existing or future formulators or manufacturers could delay clinical development or regulatory approval of our drug candidates or commercialization of any approved products. If for some reason our current contractors cannot perform as agreed, we may be required to replace them. Although we believe that there are a number of potential replacements given our formulation and manufacturing processes are not contractor specific, we may incur added costs and delays in identifying and qualifying any such replacements. Furthermore, although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug candidate to complete the trial, any significant delay in the supply of a drug candidate for an ongoing trial due to the need to replace a third-party manufacturer could delay completion of the trial.

We may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

Risks Related to Commercialization of Our Drug Candidates

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue.

We have no commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drugs that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty North American sales force that calls on a limited but focused group of physicians, we may commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population and for markets outside of North America, we may enter into arrangements with other companies for commercialization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

The development of directly acting antivirals to treat HCV, and the potential changes in market dynamics that may result from their introduction for HCV therapy, may present additional risks beyond those inherent in drug development.

We are developing multiple direct-acting antiviral, or DAA, compounds, in two distinct classes, for treatment of HCV. Other companies are also developing DAAs in these classes, as well as other classes. Until the recent introduction of DAA therapy, the standard of care for HCV infection included therapy with pegylated interferon and ribavirin. Two DAAs developed by our competitors, telaprevir (Incivek) by Vertex and boceprevir (Victrelis) by Merck, were approved by the FDA for use in combination with P/R, and became a new standard of care for genotype 1 HCV in October 2011. We cannot currently predict when or if additional compounds currently in development may again change the standard of care in the future.

The development plans for our compounds include treatment regimens with our inhibitors in combination with another DAA, or our inhibitors with one or more DAAs with or without concomitant ribavirin therapy. These development programs carry all the risks inherent in drug development activities, including the risk that they will fail to show efficacy or acceptable

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safety, as well as the risk that a safety issue related to one compound may negatively impact another compound with which it is dosed. In addition, these development programs may also be subject to additional regulatory, commercial and manufacturing risks that may be additional to the risks inherent in drug development activities.

Regulatory guidelines for approval of DAA drugs for the treatment of HCV are evolving in the United States, Europe, and other countries. We anticipate that regulatory guidelines and regulatory agency responses to our and our competitors development programs will continue to change, resulting in the risk that our activities may not meet unanticipated new standards or requirements, which could lead to delay, additional expense, or potential failure of development activities.

Furthermore, even if we or our competitors successfully develop DAAs whose use improves the current standard of care, current HCV-treating physicians, HCV patients, healthcare payers, and others may not readily accept or pay for such improvements or new treatments. In addition, because development of DAAs for HCV infection is an emerging field, the delay or failure of a competitor attempting to develop therapeutics that could have been combined with our product candidates or that are perceived to be similar to our product candidates could have a significant adverse effect on the commercial or regulatory environment for our product candidates or on the price of our stock. Other companies developing DAAs have more advanced development programs than we do. Their success or failure to successfully conclude clinical development and obtain marketing approval could have a material adverse effect on our development and commercialization plans and activities.

If our future drugs do not achieve market acceptance, we may be unable to generate significant revenue, if any.

Even if sovaprevir, ACH-3102, ACH-2684, ACH-3422 or any other drug candidates we may develop or acquire in the future obtain regulatory approval, they may not gain market acceptance among physicians, health care payors, patients and the medical community. Factors that we believe could materially affect market acceptance of our product candidates include:

- the timing of market introduction of competitive drugs;
- the demonstrated clinical safety and efficacy of our product candidates compared to other drugs and other drug candidates;
- the suitability of our drug candidates to be co-administered or combined with other drugs or drug candidates;
- the durability of our drug candidates in their ability to prevent the emergence of drug-resistant viral mutants;
- the convenience and ease of administration of our product candidates;
- the existence, prevalence and severity of adverse side effects;
- other potential advantages of alternative treatment methods;
- the effectiveness of marketing and distribution support;
- the cost-effectiveness of our product candidates; and
- the availability of reimbursement from managed care plans, the government and other third-party payors.

If our approved drugs fail to achieve market acceptance, we would not be able to generate significant revenue.

If third-party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend significantly upon the availability of adequate reimbursement for the use of any approved drug candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third party 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 reimbursement approval for a product from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of any approved drugs to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any drug

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candidate incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products or combinations of products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

In the United States, at both the federal and state levels, the government regularly proposes legislation to reform health care and its cost, and such proposals have received increasing political attention. In 2010, Congress recently passed legislation to reform the U.S. health care system by expanding health insurance coverage, reducing health care costs and making other changes. While health care reform may increase the number of patients who have insurance coverage for the use of any approved drug candidate, it may also include changes that adversely affect reimbursement for approved drug candidates. In addition, there has been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our approved products. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for any approved products could have a material adverse effect on our operating results and our overall financial condition.

Growing availability of orphan pharmaceuticals may lead to increased focus on cost containment.

Orphan pharmaceuticals refer to medicines that treat rare or life-threatening conditions that have smaller patient populations, such as certain types of cancer. The growing availability and use of innovative orphan pharmaceuticals, combined with their relative higher cost as compared to other types of pharmaceutical products, is beginning to generate significant payer interest in developing cost containment strategies targeted to this sector. While the impact on our payers efforts to control access and pricing of orphan pharmaceuticals has been limited to date, the increasing use of health technology assessment in markets around the world and the deteriorating finances of governments, may lead to a more significant adverse business impact on drug pricing in the future.

Healthcare reform measures, if implemented, could hinder or prevent our commercial success.

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 may adversely affect:

- the demand for any drug products for which we may 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 ability of government agencies to continue to pay for such care;

the level of taxes that we are required to pay; and

the availability of capital.

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Risks Related to Patents and Licenses

If our patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business.

We own or hold exclusive licenses to several issued patents U.S. and pending U.S. provisional and non-provisional patent applications, as well as pending PCT applications and associated non-US patents and patent applications. Our success depends in large part on our ability to obtain and maintain patent protection both in the United States and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file patent applications on, our drug candidates or their use as anti-infective drugs. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

The HCV inhibitor space is particularly crowded in terms of intellectual property, and certain competitors such as Merck, Vertex, AstraZeneca, Bayer, Gilead and Bristol-Myers Squibb, have disclosed compounds that may be prior art to our patent applications and prevent issuance or alter the scope of any claims that we may pursue related to our drug candidates.

The claims of the issued patents that are licensed to us, and the claims of any patents which may issue in the future and be owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. For instance, the issued patents relating to our drug candidates may be limited to a particular molecule. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different molecule, our patents may not prevent others from directly competing with us.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our drug candidates, thereby reducing any advantages of the patent. To the extent our drug candidates based on that technology are not commercialized significantly ahead of the date of any applicable patent, or to the extent we have no other patent protection on such product candidates, those drug candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the Federal Food, Drug and Cosmetic Act or trade secret protection.

The Leahy-Smith America Invents Act, or the America Invents Act, was signed into law in September 2011, with many of the substantive changes becoming effective one year or 18 months from its enactment. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a first to invent standard to a first to file standard and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States.

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We license patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We are party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for our business. In particular, we have obtained licenses from Yale University and Emory University with respect to elvucitabine. We may enter into additional licenses for third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Because our research and development of drug candidates incorporates compounds and other information that is the intellectual property of third parties, we depend on continued access to such intellectual property to conduct and complete our preclinical and clinical research and commercialize the drug candidates that result from this research. Some of our existing licenses impose, and we expect that future licenses would impose, numerous obligations on us. For example, under our existing and future license agreements, we may be required to pay minimum annual royalty amounts and/or payments upon the achievement of specified milestones. We may also be required to reimburse patent costs incurred by the licensor, or we may be obligated to pay additional royalties, at specified rates, based on net sales of our product candidates that incorporate the licensed intellectual property rights. We may also be obligated under some of these agreements to pay a percentage of any future sublicensing revenues that we may receive. Future license agreements may also include payment obligations such as milestone payments or minimum expenditures for research and development. In addition to our payment obligations under our current licenses, we are required to comply with reporting, insurance and indemnification requirements under the agreements. We expect that any future licenses would contain similar requirements.

If we fail to comply with these obligations or otherwise breach a license agreement, the licensor may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any drug that is covered by the licensed intellectual property. Even if we contest any such termination or claim and are ultimately successful, our financial results and stock price could suffer. In addition, upon any termination of a license agreement, we may be required to grant to the licensor a license to any related intellectual property that we developed. For example, the licensors have the right to terminate our license of the intellectual property covered by its licenses to us under certain circumstances, including our failure to make payments to the licensor when due and our uncured breach of any other terms of the licenses. If access to such intellectual property is terminated, or becomes more expensive as a result of renegotiation of any of our existing license agreements, our ability to continue development of our product candidates or the successful commercialization of our drug candidates could be severely compromised and our business could be adversely affected.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities, including any drug candidates resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, if issued, could be asserted against us. We are aware that certain third parties, including Bristol-Myers Squibb, Gilead, GlaxoSmithKline plc and Enanta Pharmaceuticals, Inc., have applications that are broadly directed to certain classes of HCV inhibitors. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or drug candidate that is the subject of the suit.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U. S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our product candidates and technology. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our drug candidates, the

pharmaceutical industry is characterized by extensive litigation regarding

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patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Under our license agreements with Yale University we have the right, but not an obligation, to bring actions against an infringing third party. If we do not bring an action within a specified number of days, the licensor may bring an action against the infringing party. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our drug candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our drug candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

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, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Because of the relative weakness of the Chinese legal system in general, and intellectual property rights in particular, we may not be able to enforce intellectual property rights in China.

The legal regime protecting intellectual property rights in China is weak. Because the Chinese legal system in general, and the intellectual property regime in particular, are relatively weak, it is often difficult to create and enforce intellectual property rights in China. Accordingly, we may not be able to effectively protect our intellectual property rights for our compounds in China.

We rely on our ability to stop others from competing by enforcing our patents, however some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many foreign countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

The rights we rely upon to protect our unpatented trade secrets may be inadequate.

We rely on unpatented trade secrets, know-how and technology, which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. We seek to protect trade secrets, in part, by entering into confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements, or may refuse to enter into such agreements with us, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or our collaboration partners, board members, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

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If we fail to maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Relating to Our Securities

We may dilute our existing stockholders in connection with capital raising activities. Additionally, the market price of our common stock may fall due to the number of freely-tradable shares available in the public market.

In connection with capital raising activities, we may be required to dilute our existing stockholders substantially. For example, since August 2008, we have issued an aggregate of 76,608,269 shares of our common stock in private and registered offerings, as well as warrants to purchase an aggregate of 13,279,028 shares of our common stock. As of June 30, 2013, we have 5,347,796 warrants outstanding. All of the shares of common stock we issued, as well as those shares issuable upon exercise of the warrants, are freely tradable pursuant to effective registration statements, making such shares available for immediate resale in the public market. In November 2012, we entered into a sales agreement with Cantor pursuant to which, from time to time, we may offer and sell shares of our common stock having an aggregate offering price of up to $50,000,000 through Cantor pursuant to a universal shelf registration statement that we filed in November 2012. Sales of our common stock, if any, under the agreement with Cantor may be made in sales deemed to be at-the-market equity offerings as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through the NASDAQ Global Select Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities could lower the market price of our common stock.

Our stock price is likely to be volatile, and the market price of our common stock may decline in value in the future.

The market price of our common stock has fluctuated in the past and is likely to fluctuate in the future. During the period from January 1, 2009 to June 30, 2013, our stock price has ranged from a low of $0.70 to a high of $12.95. Market prices for securities of early stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the results of our clinical trials of our protease inhibitors, sovaprevir and ACH-2684, our NS5A inhibitor, ACH-3102, and our nucleotide polymerase inhibitor, ACH-3422;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;

the announcements of those data, particularly at high profile medical meetings, and the investment community s perception of and reaction to those data;

the ability of our drug candidates to be dosed safely in combination with other drugs and/or drug candidates, both ours and others;

the entry into, modification of, or termination of key agreements, or any new collaboration agreement we may enter;

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market expectations about the timeliness of our entry into, or failure to enter, collaboration arrangements with third parties;

the entry by a potential third-party collaborator into an alliance with a competitor, or the entry by any other HCV drug developer into an alliance that may be perceived as competitive to us;

the continued industry consolidation of pharmaceutical companies developing HCV drug therapies, or the acquisition of any one of our HCV drug development competitors;

the premiums on other transactions and any significant increases or decreases of those premiums;

the results of regulatory reviews and actions relating to the approval of our drug candidates;

our failure to obtain patent protection for any of our drug candidates or the issuance of third party patents that cover our drug candidates;

the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;

failure of any of our drug candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect our business, financial condition and operations, including without limitation research and development expenditures;

the launch of drugs by others that would compete with our drug candidates;

the failure or discontinuation of any of our research programs;

issues in manufacturing our drug candidates or any approved products;

the introduction of technological innovations or new commercial products by us or our competitors;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock;

future sales of our common stock;

changes in the structure of health care payment systems;

period-to-period fluctuations in our financial results; and

low trading volume of our common stock.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of important clinical data or other significant information and as we announce such results and information, we expect the price of our common stock to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

Unstable market and economic conditions may have serious adverse consequences on our business.

Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, 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 would directly affect our ability to attain our operating goals on schedule and on budget.

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Our management is required to devote substantial time and incur additional expense to comply with public company regulations. Our failure to comply with such regulations could subject us to public investigations, fines, enforcement actions and other sanctions by regulatory agencies and authorities and, as a result, our stock price could decline in value.

As a public company, the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, as well as the rules of the NASDAQ Global Select Market, have required us to implement additional corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations places significant additional demands on our limited number of finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management is required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in our annual reports on Form 10-K. If we are unable to continue to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders.

ITEM 6. EXHIBITS

10.1	Employment Agreement, dated May 6, 2013 between Achillion Pharmaceuticals, Inc. and David Apelian
10.2	Employment Agreement, dated May 28, 2013 between Achillion Pharmaceuticals, Inc. and Milind Deshpande
31.1	Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.
32.2	Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	XBRL Label Linkbase Document*
101.PRE	XBRL Taxonomy Presentation Linkbase Document*

* Submitted electronically herewith
Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets at June 30, 2013 and December 31, 2012 (unaudited), (ii) Statements of Comprehensive Loss for the three and six months ended June 30, 2013 and 2012 (unaudited), (iii) Statements of Cash Flows for the six months ended June 30, 2013 and 2012 (unaudited), and (iv) Notes to Financial Statements (unaudited).

In accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

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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.

ACHILLION PHARMACEUTICALS, INC.

Date: August 7, 2013

/s/ Milind S. Deshpande
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2013

/s/ Mary Kay Fenton
Chief Financial Officer
(Principal Financial and Accounting Officer)

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