ACHILLION PHARMACEUTICALS INC
Form 10-Q
August 08, 2012
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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, 2012

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 website, 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, 2012, the registrant had 72,534,090 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, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 18,264	$ 16,110
Marketable securities	41,692	37,456
Accounts and other receivables	426	103
Prepaid expenses and other current assets	1,935	1,423
Total current assets	62,317	55,092
Marketable securities		26,377
Fixed assets, net	1,364	994
Deferred financing costs	12	15
Restricted cash	152	152
Total assets	$ 63,845	$ 82,630
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 4,868	$ 4,795
Accrued expenses	4,722	4,008
Current portion of long-term debt	339	141
Total current liabilities	9,929	8,944
Long-term debt	524	229
Deferred revenue		2,489
Total liabilities	10,453	11,662
Commitments and contingencies		
Stockholders Equity:		
Common Stock, $.001 par value; 200,000 shares authorized: 72,373 and 69,788 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	72	70
Additional paid-in capital	349,576	346,518
Accumulated deficit	(296,268)	(275,600)
Accumulated other comprehensive income (loss)	12	(20)
Total stockholders equity	53,392	70,968
Total liabilities and stockholders equity	$ 63,845	$ 82,630

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,	
	2012	2011	2012	2011
Revenue	$	$ 56	$ 2,489	$ 121
Operating expenses				
Research and development	8,979	8,896	17,921	16,889
General and administrative	2,580	2,436	5,318	4,659
Total operating expenses	11,559	11,332	23,239	21,548
Loss from operations	(11,559)	(11,276)	(20,750)	(21,427)
Other income (expense)				
Interest income	55	30	119	70
Interest expense	(23)	(4)	(37)	(26)
Net loss	(11,527)	(11,250)	(20,668)	(21,383)
Total comprehensive loss	(11,543)	(11,246)	(20,636)	(21,381)
Basic and diluted net loss per share (Note 4)	$ (0.16)	$ (0.19)	$ (0.29)	$ (0.36)
Weighted average number of shares used in computing basic and diluted net loss per share	71,211	58,938	70,811	58,665

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)

	Six Months Ended June 30,	
	2012	2011
Cash flows from operating activities		
Net loss	$ (20,668)	$ (21,383)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	209	147
Noncash stock based compensation	1,735	1,326
Noncash interest expense		9
(Gain) loss on disposal of equipment		(10)
Premium on purchases of marketable securities	(135)	(234)
Amortization of premium on marketable securities	203	197
Changes in operating assets and liabilities:		
Accounts and other receivables	(323)	(107)
Prepaid expenses and other assets	(512)	255
Accounts payable	73	1,496
Accrued expenses	714	1,674
Deferred revenue	(2,489)	
Net cash used in operating activities	(21,193)	(16,630)
Cash flows from investing activities		
Purchases of fixed assets	(576)	(497)
Purchases of marketable securities	(32,845)	(18,530)
Maturities of marketable securities	54,950	30,744
Net cash provided by investing activities	21,529	11,717
Cash flows from financing activities		
Proceeds from sale of common stock, net of issuance costs		60,960
Proceeds from exercise of stock options	1,237	480
Proceeds from sale of common stock under Employee Stock Purchase Plan	88	75
Payment of deferred financing costs		(10)
Borrowings of debt	609	438
Repayments of debt	(116)	(478)
Net cash provided by financing activities	1,818	61,465
Net increase in cash and cash equivalents	2,154	56,552
Cash and cash equivalents, beginning of period	16,110	25,373
Cash and cash equivalents, end of period	$ 18,264	$ 81,925
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 33	$ 13
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 $282,406 from inception through June 30, 2012 and had an accumulated deficit of $296,268 at June 30, 2012, 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, borrowings from debt facilities and the receipt of milestone and cost-sharing receipts from a former collaboration partner, Gilead Sciences, Inc. (Gilead).

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, 2013. 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 (formerly known as ACH-1625), ACH-2684 and ACH-3102;
- the Company s ability to, and its choice whether to, enter into corporate collaborations for its hepatitis C (HCV) candidates and the terms and success of these collaborations;
- 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 market 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.

Certain prior period amounts have been reclassified to conform to the current year s presentation. The premiums paid on the purchase of marketable securities were reclassified from investing activities to operating activities on the Statement of Cash Flows for the six months ended June 30, 2011.

2. Accounting Standards Updates

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05 Comprehensive Income: Presentation of Comprehensive Income. Under the amendment, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminated the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity. The amendment did not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. In December 2011, the FASB issued ASU No. 2011-12, Comprehensive Income: Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-05 (ASU 2011-12). ASU 2011-12 deferred changes in Update 2011-05 that relate to the presentation of reclassification adjustments. ASU 2011-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company adopted this guidance as of January 1, 2012 and elected the single continuous statement option. As this guidance relates to presentation only, the adoption of this guidance did not have any other effect on the Company s financial statements.

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS). ASU 2011-04 represents converged guidance between U.S. GAAP and IFRS resulting in common requirements for measuring fair value and for disclosing information about fair value measurements. This new guidance is effective for interim and annual periods beginning after December 15, 2011. The Company adopted this guidance as of January 1, 2012. The adoption of ASU 2011-04 did not have a material impact on the Company s condensed consolidated financial statements.

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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, 2011 included in the Company s Annual Report on Form 10-K filed with the SEC on March 8, 2012. 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 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. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated 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 stock 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 as of June 30, 2012 and 2011:

	June 30,	
	2012	2011
Options	5,975	5,607
Warrants	6,071	9,664
Total potentially dilutive securities outstanding	12,046	15,271

5. Collaboration Arrangements

Gilead Sciences, Inc.

In November 2004, the Company entered into a research collaboration and license agreement with Gilead pursuant to which the Company agreed to collaborate exclusively with Gilead to develop and commercialize compounds for the treatment of chronic hepatitis C which inhibit HCV replication through a novel mechanism of action targeting the HCV NS4A protein. In February 2012, following on-going discussions between the Company and Gilead, Gilead provided a notice of termination of the collaboration as neither party was devoting significant time to advancing the compounds under the agreement. The Company retains the right to develop ACH-1095, an NS5A antagonist, although it does not have current plans to do so.

The Company received $10,000 from Gilead upon the execution of the license agreement, of which $2,000 was allocated to the fair value of the preferred stock purchased. The remaining $8,000 of the non-refundable up-front license fee, as well as a $2,000 milestone achieved during the period prior to achievement of proof-of-concept, were accounted for under the proportionate performance model.

During the six months ended June 30, 2012 and 2011, the Company recognized revenue related to external costs billed by the company to Gilead of $0 and $121, respectively, under the license agreement.

During the six months ended June 30, 2011, the Company did not recognize any revenue related to the amortization of deferred revenue as it was unable to estimate its total performance obligations under the collaboration. During the six months ended June 30, 2012, effective with the termination of the collaboration, the Company recognized the remaining $2,489 of deferred revenue as it no longer has any future obligations under the collaboration.

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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. There was no financial impact upon the signing of the Agreement. The Company will be eligible to receive development milestones and royalties on net sales in those territories.

The Agreement may be terminated by either party based upon material breaches by the other party, effective 90 days after providing written notice to the breaching party, if the breaching party fails to cure its material breach.

The Company may terminate the Agreement upon 30 days written notice in the event GCAT fails to meet any of the development or commercialization diligence milestones by the deadlines specified in the Agreement, or may terminate upon 90 days written notice in the event of a change of corporate control. In the event of a change of control, as defined in the Agreement, the Company shall pay GCAT termination fees, in an amount determined based upon specified progress milestones.

6. 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 $41,692 and $63,833 as of June 30, 2012 and December 31, 2011, respectively, are 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 gain (loss) from marketable securities was $12 and $(20) at June 30, 2012 and December 31, 2011, respectively.

As of June 30, 2012 and December 31, 2011, none of the Company s investments were determined to be other than temporarily impaired.

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7. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2012	December 31, 2011
Accrued compensation	$ 1,353	$ 1,169
Accrued research and development expenses	2,750	2,341
Accrued professional fees	427	281
Other accrued expenses	192	217
Total	$ 4,722	$ 4,008

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.

8. Debt

Debt consists of the following:

	June 30, 2012	December 31, 2011
2011 Credit Facility, payable in monthly installments through March 2015, with fixed interest of 6.44% to 6.79% per annum	$ 863	$ 370
Total debt	863	370
Less: current portion	(339)	(141)
Total long-term debt, net of current portion	$ 524	$ 229

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 can draw down equipment loan advances for the purchase of new laboratory equipment through March 2013. The purchased equipment serves as collateral for the 2011 Credit Facility. Through June 30, 2012, the Company had drawn 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.

9. Stock Based Compensation

The Company s 2006 Stock Incentive Plan, (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 7,215 shares available to be granted under the 2006 Plan as of June 30, 2012.

A summary of the status of the Company s stock option activity for the six months ended June 30, 2012 is presented in the table and narrative below:

	Options	Weighted Average Exercise Price
Outstanding at January 1, 2012	6,610	$ 4.40
Granted	217	6.85
Exercised	(500)	2.48
Cancelled	(20)	1.92
Forfeited	(332)	5.26
Outstanding at June 30, 2012	5,975	$ 4.61
Options exercisable at June 30, 2012	3,241	$ 4.52
Weighted-average fair value of options granted during the period		$ 4.93

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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, 2012	June 30, 2011
Expected term of option	5.0 - 6.1 years	5.0 - 6.1 years
Expected volatility	88%	87%
Risk free interest rate	0.92 - 1.33%	2.13 - 2.57%
Expected dividend yield	0%	0%

Total compensation expense recorded in the accompanying statements of comprehensive loss associated with option grants made to employees was $761 and $616 for the three months ended June 30, 2012 and 2011, respectively. Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees was $1,602 and $1,213 for the six months ended June 30, 2012 and 2011, 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, 2012, the intrinsic value of the options outstanding was $13,957, of which $8,576 related to vested options and $5,381 related to unvested options. The intrinsic value of stock options is calculated based on the difference between the exercise prices of the common stock underlying the awards and the quoted stock price of the Company s common stock as of the reporting date.

As of June 30, 2012, the total compensation cost related to unvested options not yet recognized in the financial statements is approximately $7,861, net of estimated forfeitures, and the weighted average period over which this amount is expected to be recognized is 1.5 years.

10. Stockholders Equity

Changes in stockholders equity for the six months ended June 30, 2012 and 2011 were as follows:

	For the Six Months Ended June 30,	
	2012	2011
Balance at December 31, 2011 and 2010	$ 70,968	$ 50,544
Net loss	(20,668)	(21,383)
Stock based compensation	1,735	1,326
Exercise of stock options	1,237	480
Change in unrealized gain on marketable securities	32	2
Issuance of common stock		60,960
Issuance of common stock under the Employee Stock Purchase Plan	88	75
Balance at June 30, 2012 and 2011	$ 53,392	$ 92,004

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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 Part II, 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 infection, or HCV, and the development of antibacterials for the treatment of resistant bacterial infections. We are currently focusing our efforts on developing the following drug candidates for the treatment of HCV:

- Sovaprevir, formerly ACH-1625, a NS3 protease inhibitor for the treatment of HCV, currently in phase II clinical development;
- ACH-2684, a NS3 protease inhibitor for the treatment of HCV, currently in phase I clinical development;
- ACH-2928, a NS5A inhibitor for the treatment of HCV, which recently completed phase I clinical development; and
- ACH-3102, a NS5A inhibitor for the treatment of HCV, currently in phase I clinical development.

In addition, we have established a pipeline of certain antibacterial product candidates for which we are currently seeking appropriate collaborative partners, but to which we are not devoting significant resources at this time. These product candidates include ACH-702 for the treatment of dermatologic and ophthalmic infections, and ACH-2881 for the treatment of serious resistant bacterial infections, including methicillin resistant staphylococcus aureus.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of $282 million from inception through June 30, 2012 and had an accumulated deficit of $296 million at June 30, 2012, which includes preferred stock dividends recognized until our initial public offering in 2006. Our net losses were $20.7 million and $21.4 million for the six months ended June 30, 2012 and 2011, 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 public offerings of our common stock in January 2010 and June 2011;
- borrowings from debt facilities; and
- receipts from up-front and milestone payments, as well as cost-sharing receipts, from our former collaboration partner, Gilead Sciences, Inc., or Gilead.

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

continue clinical testing of sovaprevir, formerly ACH-1625, ACH-2684, and ACH-3102; 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 companies at our current stage of development, there can be no assurance that we will successfully complete our research and development, obtain adequate patent protection for our technology, obtain necessary

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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 chronic hepatitis C. During the six months ended June 30, 2012 and 2011 we recognized $2.5 million and $121,000, respectively, under this collaboration agreement.

Upon initiating the collaboration with Gilead in 2004, we received a payment of $10.0 million, which included an equity investment by Gilead determined to be worth approximately $2.0 million. The remaining $8.0 million, as well as a $2.0 million milestone achieved during the period prior to proof-of-concept, was accounted for under the proportionate performance model. Revenue under the proportionate performance model was recognized as effort under the collaboration was incurred. Payments made by us to Gilead in connection with this collaboration were recognized as a reduction of revenue.

In February 2012, following on-going discussions between us and Gilead, Gilead provided a notice of termination of the collaboration as neither party was devoting significant time to advancing the compounds under the agreement. We retain the right to develop ACH-1095, although we do not have current plans to do so.

We did not recognize any revenue related to the amortization of deferred revenue during the six months ended June 30, 2011, as we were unable to accurately estimate our total performance obligations under the Gilead collaboration. Effective with the February 2012 termination of the collaboration, we recognized the remaining $2.5 million of deferred revenue.

Research and Development

Our research and development expenses reflect costs incurred for our proprietary research and development projects as well as costs for research and development projects conducted as part of collaborative arrangements. 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.

We have established our current drug candidate pipeline primarily through our internal discovery capabilities except for elvucitabine, which we in-licensed. Through these efforts we have identified and are developing the following drug candidates and programs:

Sovaprevir (formerly ACH-1625), a NS3 Protease Inhibitor for Chronic HCV Infection. In April 2012, we announced data from an on-going phase IIa clinical trial conducted in both the United States and Europe to assess sovaprevir s safety, tolerability, pharmacokinetic properties and efficacy in treatment-naïve genotype 1 HCV-infected subjects. In this trial, patients received sovaprevir at doses of 200mg, 400mg and 800mg once-daily in combination with pegylated interferon alpha and ribavirin, or P/R. Sovaprevir was demonstrated to achieve a complete early virologic response, or cEVR, 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 transient with all patients returning to baseline values while on treatment, and attributable to non-drug-related factors. The phase IIa clinical trial is continuing with certain patients receiving P/R therapy for up to 48 weeks. In August 2012, we announced Sustained Viral Response four weeks (SVR4) after the completion of 24 weeks of therapy consisting of 12 weeks of sovaprevir and P/R followed by additional 12 weeks of P/R. In all, 39 patients were assigned to receive 24 weeks of therapy with the remaining 18 patients assigned to receive an additional 36 weeks of P/R. The SVR4 rates were 90%; 85%; and 100% in the 200 mg, 400 mg, and 800 mg dose groups, respectively. Additional SVR data will be presented when all patients complete their four and twelve week post-treatment visits, expected in the first quarter of 2013. Sovaprevir was also demonstrated to show efficacy in a pilot study of treatment-naïve patients infected with genotype 3 HCV. In addition, mutations commonly associated with protease inhibitor therapy including mutations at R155, A156 and D168 were not observed with sovaprevir treatment. In December 2011, sovaprevir was granted Fast Track status by the United States Food and Drug Administration, or FDA.

ACH-2684, a NS3 Protease Inhibitor for Chronic HCV Infection. In preclinical studies, ACH-2684 has demonstrated excellent potency, as well as good pharmacokinetic and safety profiles. Pharmacokinetics refers to the way in which the compound is taken into, moves through, and is eliminated from the body. The potency and virology profiles of ACH-2684 demonstrate that it effectively suppresses a broad range of viral subtypes and natural variants of HCV, and may be effective in the prevention and treatment of emerging resistant variants. This compound also retains

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potent *in vitro* activity against all known HCV genotypes 1-6. In preclinical studies, ACH-2684 was effective in combination with other HCV inhibitors, and *in vitro* is synergistic with NS5B nucleoside polymerase inhibitors. In phase I clinical studies, twice daily doses of 400mg of ACH-2684 reduced viral load by a maximal 4.63 $\log_{10}$ in genotype 1 HCV patients and by a maximal 2.03 $\log_{10}$ in genotype 3 HCV patients. Additionally, once daily doses of 400mg of ACH-2684 reduced viral load by a mean maximum 3.73 $\log_{10}$ in patients with HCV genotype 1. The compound demonstrated good safety and tolerability both in healthy volunteers and in patients with HCV in all segments of these phase 1 clinical trials. Additional arms of this phase I trial in HCV-infected patients remain on-going.

ACH-2928, a NS5A Inhibitor for Chronic HCV Infection. In preclinical studies, this compound demonstrated excellent potency against HCV replication, as well as good pharmacokinetic and safety profiles. ACH-2928 is highly active and potent against HCV genotypes 1a and 1b, as well as across other genotypes. We believe the high potency of ACH-2928, in the picomolar range, and its favorable pharmacokinetic properties, strongly suggest once-daily dosing. Importantly, NS5A inhibitors have been demonstrated in clinical trials to be highly effective in combination with NS3 protease inhibitors, and in *in vitro* studies to be highly effective in combination with NS5B polymerase inhibitors, interferon and ribavirin. In phase I clinical studies, ACH-2928 was demonstrated to reduce viral load by a maximal 4.86 $\log_{10}$ and was safe and well-tolerated. Within the NS5A class of compounds, our future clinical focus will be on ACH-3102 due to that compound s differentiated resistance profile.

ACH-3102, a NS5A Inhibitor for Chronic HCV Infection. In preclinical studies, ACH-3102 has demonstrated potent pan-genotypic activity, meaning activity against HCV subtypes referred to as genotypes 1 through 6, including excellent activity against both the 1a genotype and known mutant variants of genotype 1 HCV. We filed an IND for ACH-3102 in March 2012 and initiated a phase 1 human clinical trial in May 2012 which remains on-going. In August 2012, we reported that 42 healthy volunteers have received a single dose of ACH-3102, ranging from 25 mg to 1,000 mg, and 24 healthy volunteers have received 14 days of once daily ACH-3102, with doses ranging from 25 mg to 75 mg. Preliminary data from both the single and multiple ascending dose groups demonstrated that ACH-3102 was well tolerated with no serious adverse events, no clinically significant changes in vital signs, electrocardiograms (ECGs), or laboratory evaluations. All reported adverse events were classified as mild or moderate, and were transient in nature. The Phase 1 trial has begun enrolling patients with genotype 1 HCV and results are expected to be reported in the third quarter of 2012. In May 2012, ACH-3102 was granted Fast Track status by the FDA.

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 candidates are expensed as incurred as indirect costs.

	Six Months Ended June 30,	
	2012	2011
	(in thousands)	
Clinical candidate direct external costs:		
Sovaprevir, formerly ACH-1625 (and related compounds)	$ 4,846	$ 6,867
ACH-2684 (and related compounds)	1,417	2,668
ACH-2928 (and related compounds)	522	1,586
ACH-3102 (and related compounds)	4,339	
Other	570	92
	11,694	11,213
Direct internal personnel costs	4,723	3,765
Sub-total direct costs	16,417	14,978
Indirect costs and overhead	1,607	1,984
Research and development tax credit	(103)	(73)

Total research and development	$ 17,921	$ 16,889

We are currently conducting phase II clinical trials of sovaprevir and phase I clinical trials of ACH-2684 and ACH-3102.

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.

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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, 2011. 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 2012, there were no significant changes in our estimates and critical accounting policies.

Results of Operations

Results of operations may vary from period to period depending on numerous factors, including the timing of payments received under existing or future strategic alliances, joint ventures or financings, if any, the progress of our research and development projects, technological advances and determinations as to the commercial potential of proposed products.

Comparison of Three and Six Months Ended June 30, 2012 and 2011

Revenue. We recognized revenue of $0 and $56,000 for the three months ended June 30, 2012 and 2011, and $2.5 million and $121,000 for the six months ended June 30, 2012 and 2011, respectively. The increase in revenue in 2012 is primarily related to the recognition of $2.5 million of deferred revenue related to our former collaboration with Gilead, which was terminated in February 2012.

During the three and six months ended June 30, 2011, revenue related to external costs incurred by us and shared with Gilead. During this period, we were unable to estimate our future performance obligations under the collaboration, and therefore, ceased recognizing revenue related to upfront, milestone and full time equivalent payments previously received until we could reasonably estimate our total future performance obligations. During the six months ended June 30, 2012, effective with the termination of the collaboration, we recognized the remaining $2.5 million of deferred revenue as we no longer have any future obligations under the collaboration.

Research and Development Expenses. Research and development expenses were $9.0 million and $8.9 million for the three months ended June 30, 2012 and 2011, respectively, and $17.9 million and $16.9 million for the six months ended June 30, 2012 and 2011, respectively. The increase for the three and six months ended June 30, 2012 was primarily due to increased personnel costs related to the addition of personnel in our development group, and expenses related to preclinical and clinical testing of ACH-3102, partially offset by decreased clinical trial expenses for ACH-1625 and ACH-2684 during the three months ended June 30, 2012. We expect research and development expenses to remain materially consistent with the first half of 2012 during the remainder of the year, as we continue clinical testing of sovaprevir (formerly ACH-1625), ACH-2684, and ACH-3102. Research and development expenses for the three and six months ended June 30, 2012 and 2011 are comprised as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	Change	2012	2011	Change
Personnel costs	$ 2,160	$ 1,593	$ 567	$ 4,105	$ 3,220	$ 885
Stock based compensation	233	277	(44)	618	543	75
Outsourced research and supplies	5,636	6,129	(493)	11,071	11,070	1
Professional and consulting fees	382	397	(15)	1,093	1,050	43
Facilities costs	513	460	53	1,005	933	72
Travel and other costs	88	80	8	132	146	(14)
Research and development tax credit	(33)	(40)	7	(103)	(73)	(30)
Total	$ 8,979	$ 8,896	$ 83	$ 17,921	$ 16,889	1,032

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General and Administrative Expenses. General and administrative expenses were $2.6 million and $2.4 million for the three months ended June 30, 2012 and 2011, respectively, and $5.3 million and $4.7 million for the six months ended June 30, 2012 and 2011, respectively. The increase for the three and six months ended June 30, 2012 was primarily due to an increase in professional and consulting fees including corporate legal fees, directors compensation and business development consulting fees. Non-cash charges related to stock based compensation also increased. 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, 2012 and 2011 are comprised as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	Change	2012	2011	Change
Personnel costs	$ 708	$ 755	$ (47)	$ 1,549	$ 1,520	$ 29
Stock based compensation	582	401	181	1,117	783	334
Professional and consulting fees	762	688	74	1,635	1,255	380
Facilities costs	279	282	(3)	494	515	(21)
Travel and other costs	249	310	(61)	523	586	(63)
Total	$ 2,580	$ 2,436	$ 144	$ 5,318	$ 4,659	$ 659

Other Income (Expense). Interest income was $55,000 and $30,000 for the three months ended June 30, 2012 and 2011, respectively. The increase was primarily due to increased average cash balances in 2012. Interest expense was $23,000 and $4,000 for the three months ended June 30, 2012 and 2011, respectively. The increase was primarily due to higher average debt facility balances outstanding in 2012.

Interest income was $119,000 and $70,000 for the six months ended June 30, 2012 and 2011, respectively. The increase was primarily due to increased average cash balances in 2012. Interest expense was $37,000 and $26,000 for the six months ended June 30, 2012 and 2011, respectively. The increase 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 the issuance of stock and borrowings under debt facilities, as well as through receipts from our former collaboration with Gilead. Through June 30, 2012, we have received approximately $332.2 million in aggregate gross proceeds from stock issuances, including convertible preferred stock, our initial public offering, our 2008 and 2010 private placements and our 2010 and 2011 public offerings, $19.5 million from Gilead under our collaboration agreement and approximately $23.2 million under debt facilities. As of June 30, 2012, our debt balance due to borrowings was $863,000 with a weighted average interest rate of 6.56%.

We had $60.0 million and $79.9 million in cash, cash equivalents and marketable securities as of June 30, 2012 and December 31, 2011, respectively. We regularly review our investments and monitor the financial markets. As of June 30, 2012, our cash, cash equivalents and marketable securities included 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 $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 operating activities was $16.6 million for the six months ended June 30, 2011 and was primarily attributable to our $21.4 million net loss, partially offset by non-cash stock based compensation, combined with increases in accounts payable and accrued expenses.

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 investing activities was $11.7 million for the six months ended June 30, 2011 and was primarily attributable to the maturities of marketable securities offset by purchases of marketable securities.

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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. Cash provided by financing activities was $61.5 million for the six months ended June 30, 2011 and was primarily attributable to $61.0 million in net proceeds from the sale of 11,040,000 shares of common stock in June 2011.

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, formerly ACH-1625, ACH-2684 and ACH-3102; and
- identify and progress additional drug candidates.

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, 2013. 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, formerly ACH-1625, ACH-2684 and ACH-3102;
- our ability to, and our choice whether to, enter into corporate collaborations for our HCV candidates and the terms and success of these collaborations;
- 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 market 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.

Any future equity funding may dilute the ownership of our equity investors.

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

None.

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 six months and no security with an effective duration in excess of twelve months, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, 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, 2012. 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, 2012, 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, 2012 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.

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, formerly ACH-1625, and ACH-2684, and our NS5A inhibitors, ACH-2928 and ACH-3102. 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 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 the drugs, whether alone or in collaboration with others;

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

our ability to identify, enter into and maintain collaboration agreements with appropriate strategic partners for our compounds.

We are currently conducting a phase IIa clinical trial for sovaprevir and phase I clinical trials for ACH-2684 and ACH-3102. 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 of sovaprevir, ACH-2684, ACH-2928, ACH-3102 or the completed clinical trials for sovaprevir, ACH-2684 or ACH-2928, 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.

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, 2012, our accumulated deficit was approximately $296 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.

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, formerly ACH-1625, and ACH-2684, and our NS5A inhibitors, ACH-2928 and ACH-3102, would compete with drugs currently approved for the treatment of HCV, e.g., 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) or generic versions sold by various companies, as well as recently-approved protease inhibitors telaprevir (Incivek) by Vertex and boceprevir (Victrelis) by Merck. In addition, our HCV compounds may compete with the interferon- and ribavirin-based drugs currently in development such as Valeant s ribavirin analog (Viramidine) and Bristol - Myers Squibb s interferon lambda, and with other products in development in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors, toll-like receptor inhibitors and cyclophilin inhibitors also under development for the treatment of HCV by companies such as Abbott, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Enanta, Gilead, GlaxoSmithKline, Idenix, Johnson & Johnson, Presidio, Medivir, Merck, Novartis, Pfizer, Roche, Valeant and Vertex.

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.

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Competitive products, or specific classes 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 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 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, 2013. 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, formerly ACH-1625, and ACH-2684, and our NS5A inhibitor, ACH-3102;
- our ability to enter into corporate collaborations for our HCV candidates and the terms and success of these collaborations;
- 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 market 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 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 your rights as a stockholder. Since August 2008, we have issued an aggregate of 53,346,006 shares of our common stock in two private placements and two public offerings as well as warrants to purchase an aggregate of 9,599,950 shares of our common stock. 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 have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us.

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. Key members of our senior team include Michael Kishbauch, our president and chief executive officer, and Dr. Milind Deshpande, our president of research and development and chief scientific officer. All of our employment agreements with our senior management employees are

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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.

Our business has a substantial risk of product liability claims. If we are unable to obtain 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 amount equal to up to $10.0 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;

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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;

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 recently commercially launched direct acting antivirals, or DAAs, telaprevir (Incivek) or boceprevir (Victrelis), as well as other experimental therapies under development, or participants may drop out of our clinical trials at a higher rate than we currently anticipate, 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 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, in the phase IIa clinical study currently on-going, sovaprevir, formerly ACH-1625, is being studied in combination with the current standard of care. Recently approved therapies, including telaprevir (Incivek) and boceprivir (Victrelis) could result in a change to the standard of care which 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.

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.

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, formerly ACH-1625, ACH-2684, ACH-2928, ACH-3102 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 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.

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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 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. 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. 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

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 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.

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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, as we advance sovaprevir, formerly ACH-1625, into longer term clinical trials in phase II, we have 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 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, formerly ACH-1625, 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 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.

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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.

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 have an existing arrangement with GCA Therapeutics, LTD, or GCAT, for the development and commercialization of our HIV drug candidate, elvucitabine, in mainland China, Hong Kong, and Taiwan. We may enter into additional license arrangements in the future.

We also may enter into 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 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. At this time, we do not plan to clinically advance our antibacterial drug candidates, ACH-702 and ACH-2881, independently.

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,

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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.

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.

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.

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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 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 recently approved by the FDA. We cannot currently predict with any certainty the impact of the commercial launch of these compounds or any other compounds on the HCV market, although marketed DAAs may now be added to that standard regimen.

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 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 physicians and patients do not accept our future drugs, we may be unable to generate significant revenue, if any.

Even if sovaprevir, formerly ACH-1625, ACH-2684, ACH-2928, ACH-3102 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, and the impact of the recent commercial launch of telaprevir (Incivek) by Vertex and boceprevir (Victrelis) by Merck;

- 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;

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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 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. 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.

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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.

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 we are aware that 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. For example, with regard to ACH-2928, we are aware that this compound and closely related inhibitors have been disclosed in third party published patent applications and ultimately could be deemed to constitute prior art. These competitive activities may substantially impact our ability to obtain patent protection on our lead drug candidates and/or to commercialize such drug candidates in the absence of patent rights from one or more third parties.

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

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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 in one year or 18 months. 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 new legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States.

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

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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 HCV inhibitors. Certain of these third parties, in particular Gilead and Enanta, have patent applications with pending claims that, if issued, could be construed to encompass our drug candidate, ACH-2928. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, 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.

As a result of intellectual property infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also affect our potential collaborators to the extent we have any collaborations then in place, which would also affect the success of the collaboration and therefore us.

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 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.

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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 the 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 in China under the GCAT agreement.

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.

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.

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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 be required to dilute our existing stockholders further in connection with capital raising activities. Additionally, the market price of our common stock may fall due to the increased number of shares available in the public market.

In connection with capital raising activities, we may be required to dilute our existing stockholders substantially. For example, in June 2011 we issued an aggregate of 11,040,000 shares of our common stock in a public offering. In August 2010, we issued an aggregate of 19,775,101 shares of our common stock, plus common stock warrants to purchase a total of 6,921,286 additional shares of common stock in a private placement. In January and February 2010, we issued an aggregate of 11,816,250 shares of our common stock in an underwritten offering. Additionally, in August 2008, we issued 10,714,655 shares of our common stock, plus common stock warrants to purchase a total of 2,678,664 additional shares of common stock in a private placement. Stockholders will be further diluted if, and to the extent, any investors exercise their warrants. The issuance of these shares and warrants resulted in substantial dilution to stockholders who held our common stock prior to the issuance. 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 registration statements filed with the SEC that were declared effective by the SEC on April 25, 2011, September 30, 2010, October 16, 2009 and October 30, 2008, making such shares available for immediate resale in the public market.

In addition, amounts remain available for the future issuance of common stock, preferred stock and/or warrants that we may issue from time to time under the shelf registration statement on Form S-3 that we filed in March 2011. If we issue additional securities pursuant to this shelf registration statement, these securities would be available for immediate resale in the public market.

The market price of our common stock could fall due to an increase in the number of shares available for sale in the public market.

Our executive officers, directors and principal stockholders own a large percentage of our voting common stock and could limit our stockholders influence on corporate decisions or could delay or prevent a change in corporate control.

As of August 1, 2012, our directors, executive officers and current holders of more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 30% of our outstanding common stock. As a result, these stockholders, if acting together, have the ability to determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interest of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

- delaying, deferring or preventing a change in control of our company;
- entrenching our management and/or board;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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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, 2007 to August 1, 2012, our stock price has ranged from a low of $0.68 to a high of $19.61. 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, formerly ACH-1625, and ACH-2684 and our NS5A inhibitors, ACH-2928 and ACH-3102;
- 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;
- 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 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 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.

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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.

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 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	2006 Stock Incentive Plan, as amended.
10.2	Letter Agreement, dated June 25, 2012, by and between Dr. Elizabeth A. Olek and the Registrant.
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*

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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, 2012 and December 31, 2011 (unaudited), (ii) Statements of Comprehensive Loss for the three and six months ended June 30, 2012 and 2011 (unaudited), (iii) Statements of Cash Flows for the six months ended June 30, 2012 and 2011 (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 8, 2012

/s/ Michael D. Kishbauch
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2012

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

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