Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2011

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 ☒ 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 ☒ 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	☐
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 ☒

As of August 1, 2011, the registrant had 69,718,728 shares of Common Stock, $0.001 par value per share, outstanding.

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Achillion Pharmaceuticals, Inc.
Balance Sheets
(in thousands, except per share amounts)
(Unaudited)

	June 30, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 81,925	$ 25,373
Marketable securities	17,652	29,827
Accounts and other receivables	363	246
Prepaid expenses and other current assets	1,907	2,052
Total current assets	101,847	57,498
Fixed assets, net	825	468
Deferred financing costs	10	117
Restricted cash	152	152
Total assets	$ 102,834	$ 58,235
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,168	$ 2,672
Accrued expenses	3,735	2,061
Current portion of long-term debt	137	469
Total current liabilities	8,040	5,202
Long-term debt	301	—
Deferred revenue	2,489	2,489
Total liabilities	10,830	7,691
Commitments and contingencies		
Stockholders' Equity:		
Common Stock, $.001 par value; 200,000 and 100,000, respectively, shares authorized: 69,719 and 58,376 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	70	58
Additional paid-in capital	344,707	281,878
Accumulated deficit	(252,777)	(231,394)
Accumulated other comprehensive income	4	2
Total stockholders' equity	92,004	50,544
Total liabilities and stockholders' equity	$ 102,834	$ 58,235

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

Achillion Pharmaceuticals, Inc.
Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
Revenue	$ 56	$ 187	$ 121	$ 261
Operating expenses				
Research and development	8,896	4,814	16,889	8,773
General and administrative	2,436	1,690	4,659	3,357
Total operating expenses	11,332	6,504	21,548	12,130
Loss from operations	(11,276)	(6,317)	(21,427)	(11,869)
Other income (expense)				
Interest income	30	15	70	25
Interest expense	(4)	(82)	(26)	(176)
Net loss	(11,250)	(6,384)	(21,383)	(12,020)
Basic and diluted net loss per share (Note 5)	$ (0.19)	$ (0.17)	$ (0.36)	$ (0.32)
Weighted average shares used in computing basic and diluted net loss per share	58,938	38,540	58,665	37,066

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

Achillion Pharmaceuticals, Inc.
Statements of Cash Flows
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2011	2010
Cash flows from operating activities		
Net loss	$ (21,383)	$ (12,020)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	147	372
Noncash stock based compensation	1,326	938
Noncash interest expense	9	26
(Gain) loss on disposal of equipment	(10)	4
Amortization of premium on marketable securities	197	88
Changes in operating assets and liabilities:		
Accounts receivable	(107)	(122)
Prepaid expenses and other assets	255	(435)
Accounts payable	1,496	68
Accrued expenses	1,674	(413)
Net cash used in operating activities	(16,396)	(11,494)
Cash flows from investing activities		
Purchases of fixed assets	(497)	(155)
Purchases of marketable securities	(18,764)	(5,665)
Maturities of marketable securities	30,744	300
Net cash provided by (used in) by investing activities	11,483	(5,520)
Cash flows from financing activities		
Proceeds from sale of common stock, net of issuance costs	60,960	22,628
Proceeds from exercise of stock options	480	—
Proceeds from sale of common stock under Employee Stock Purchase Plan	75	50
Payment of deferred financing costs	(10)	—
Borrowings of debt	438	—
Repayments of debt	(478)	(1,148)
Net cash provided by financing activities	61,465	21,530
Net increase in cash and cash equivalents	56,552	4,516
Cash and cash equivalents, beginning of period	25,373	9,712
Cash and cash equivalents, end of period	$ 81,925	$ 14,228
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 13	$ 138

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

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 $238,915 from inception through June 30, 2011 and had an accumulated deficit of $252,777 at June 30, 2011, 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 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, 2012. 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 the Company's protease inhibitors, ACH-1625 and ACH-2684, and its NS5A inhibitors, ACH-2928 and related compounds;
- our ability to enter into corporate collaborations for our HCV candidates and the terms and success of these collaborations;
- any partnership opportunities that may arise for elvucitabine, ACH-702 or ACH-2881 that we determine to pursue;
- 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.

2. Accounting Standards Updates

In October 2009, an update was made to ASC 605, *Revenue Recognition,* which provides accounting principles and application guidance on how revenue arrangements with multiple deliverables should be separated and the consideration allocated. Assuming other criteria are met, this guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition. Allocation of consideration is now based on management's estimate of the selling price for an undelivered item where there is no other means to determine the fair value of that undelivered item. This update is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company adopted this guidance as of January 1, 2011. There was no impact to the Company's financial statements upon adoption of this standard as there were no new or modified agreements.

In May 2011, the FASB issued ASU No. 2011-04 "Fair Value Measurement: Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs". The amendments clarify the FASB's intent about the application of existing fair value measurement and disclosure requirements and in some instances change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. Notable changes under the

amended guidance include: (i) application of the highest and best use and valuation premise concepts solely for non-financial assets and liabilities; (ii) measuring the fair value of an instrument classified in a reporting entity's shareholders' equity; and (iii) disclosing quantitative information about unobservable inputs used in the fair value measurement within Level 3 of the fair value hierarchy. For public entities, the amendment is effective for interim and annual periods beginning after December 15, 2011. Early application is not permitted. The Company is currently evaluating the disclosure requirements related to providing quantitative information about unobservable inputs used to measure the fair value of its contingent consideration liability.

In June 2011, the FASB issued ASU No. 2011-05 "Comprehensive Income: Presentation of Comprehensive Income." Under the amendment, an entity will have 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, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does 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. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will not have any other effect on the Company's financial statements.

3. Basis of Presentation

The accompanying unaudited financial statements of the Company should be read in conjunction with the audited financial statements and notes as of and for the year ended December 31, 2010 included in the Company's Annual Report on Form 10-K filed with the SEC on March 3, 2011. 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. Financing Activities

Public Offering

In June 2011, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC, as underwriters (the "Underwriters"), related to a public offering of shares of the Company's common stock, par value $.001 per share, at a price of $5.90 per share less underwriting discounts and commissions (the "Offering"). The Company issued and sold an aggregate of 11,040 shares of common stock in connection with the Offering and the exercise of the over-allotment option that was granted to the underwriters in the Underwriting Agreement.

The Offering resulted in net proceeds to the Company of $60,960. The Company intends to use the net proceeds to continue clinical testing of ACH-1625, ACH-2684, and ACH-2928, to progress additional NS5A HCV drug candidates and for general corporate expenses.

5. 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 shares outstanding for the dilutive effect of common stock options and warrants. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. Securities that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been antidilutive. Potentially dilutive securities were as follows for the three and six months ended June 30, 2011 and 2010:

	Three and Six Months Ended June 30,	
	2011	2010
Options	5,607	3,336
Warrants	9,664	2,785
Total potentially dilutive securities outstanding	15,271	6,121

6. Collaboration Arrangements

Gilead Sciences, Inc.

In November 2004, the Company entered into a research collaboration and license agreement with Gilead Sciences, Inc. pursuant to which the Company agreed to collaborate exclusively with Gilead throughout the world to develop and commercialize compounds for the treatment of chronic hepatitis C and which inhibit HCV replication through a novel mechanism of action targeting the HCV NS4A protein. In September 2009, the Company and Gilead amended the collaboration arrangement so that the Company may continue to develop ACH-1095 independently during an "Interim Period," while Gilead may rejoin in the development of ACH-1095 at clinical proof-of-concept, as defined. At this time, however, the Company has elected not to devote significant resources to clinical development of ACH-1095.

The Company continues to be responsible for preclinical assessment of a limited number of other NS4A antagonists until such time as proof-of-concept is achieved. Gilead will otherwise be responsible for all manufacturing, formulation and commercialization activities associated with such compounds, if nominated, including all regulatory filings and clinical trials after proof-of-concept. 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 concurrent with entering the license agreement. 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, are being accounted for under the proportionate performance model.

Under collaboration arrangements, payments received during the period of performance generally include up-front payments, time-or performance-based milestones and reimbursement of internal and external costs. The proportion of actual performance to total expected performance is applied to these payments in determining periodic revenue. Revenue recognized will be limited by the aggregate cash received or receivable to date by the Company. Payments to Gilead under this collaboration are recognized as a reduction in revenue.

At this time, the Company cannot accurately estimate its future obligations under the collaboration as it has not identified a new lead compound that will be developed jointly. Therefore, during the three and six months ended June 30, 2011 and 2010, the Company did not recognize revenue from upfront, milestone and full-time equivalent, or "FTE," fees previously received under the collaboration. The Company will determine its remaining obligations if and when a new lead compound is identified.

During the three months ended June 30, 2011 and 2010, the Company recognized revenue of $56 and $43, respectively, under the arrangement, all of which related to external costs billed by the Company to Gilead. During the six months ended June 30, 2011 and 2010, the Company recognized revenue of $121 and $117, respectively, under the Gilead Arrangement, all of which related to external costs billed by the Company to Gilead.

Included in the accompanying balance sheets as of June 30, 2011 and December 31, 2010 are $56 and $18, respectively, of accounts receivable resulting from this collaboration agreement and $2,489 and $2,489, respectively, of deferred revenue resulting from the up-front fee, a milestone payment, and FTE costs.

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, the Company shall pay GCAT termination fees, in an amount determined based upon specified progress milestones.

7. Marketable Securities

The Company applies the provisions of 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 $17,652 and $29,827 as of June 30, 2011 and December 31, 2010, respectively, is valued based on level 2 inputs. The Company's investments consist mainly of U.S government and agency securities, government sponsored bond obligations and certain other corporate debt securities. Fair value is determined based upon quoted market prices; however, due to lack of sufficiency of transactions and trading volume, 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*. The maturities of all marketable securities held at June 30, 2011 are less than one year. 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 from marketable securities was $4 and $2 at June 30, 2011 and December 31, 2010, respectively.

As of June 30, 2011 and December 31, 2010, none of the Company's investments were determined to be other than temporarily impaired.

8. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2011	December 31, 2010
Accrued compensation	$ 1,102	$ 978
Accrued research and development expenses	1,824	676
Accrued professional fees	642	317
Other accrued expenses	167	90
Total	$ 3,735	$ 2,061

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

9. Debt

Debt consists of the following:

	June 30, 2011	December 31, 2010
2011 Credit Facility, payable in monthly installments through June 2014, with fixed interest of 6.79%	$ 438	$ —
2008 Credit Facility, payable in monthly installments as notes matured through March 2011, with interest of 9.97% to 11.58% per annum	$ —	$ 469
Total debt	438	469
Less: current portion	137	(469)
Total long-term debt, net of current portion	$ 301	$ —

In March 2011, the Company entered into a Master Security Agreement for a $2,000 Capital Expenditure Line of Credit, ("the 2011 Credit Facility"). Under the 2011 Credit Facility, the Company may take equipment loan advances for the purchase of new laboratory equipment through March 2012. In June 2011, the Company took a $438 advance under the 2011 Credit Facility.

10. Stock Based Compensation

The Company's 2006 Stock Incentive Plan, or the 2006 Plan, is administered by the Company's Board of Directors and provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights and other stock based awards. The Company's officers, employees, consultants, advisors and directors are eligible to receive awards under the 2006 Plan; however, incentive stock options may only be granted to employees. Options granted are exercisable for a period determined by the Company, but in no event longer than ten years from the date of the grant. Options generally vest ratably over four years. There were 1,151 shares available to be granted under the 2006 Plan as of June 30, 2011.

A summary of the status of the Company's stock option activity for the six months ended June 30, 2011 is presented in the table and narrative below:

	Options	Weighted Average Exercise Price
Outstanding at January 1, 2011	5,860	$ 3.67
Granted	24	5.78
Exercised	(272)	1.77
Cancelled/Forfeited	(5)	1.53
Outstanding at June 30, 2011	5,607	$ 3.77
Options exercisable at June 30, 2011	2,396	$ 4.84
Weighted-average fair value of options granted during the period		$ 4.27

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, 2011	June 30, 2010
Expected term of option	5.0 - 6.1 years	6.1 years
Expected volatility	87%	86%
Risk free interest rate	2.13 - 2.57%	2.92%
Expected dividend yield	0%	0%

Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees was $616 and $455 for the three months ended June 30, 2011 and 2010, respectively. Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees was $1,213 and $913 for the six months ended June 30, 2011 and 2010, 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, 2011, the intrinsic value of the options outstanding was $23,156, of which $8,808 related to vested options and $14,348 related to unvested options. The intrinsic value of stock options is calculated based on the difference between the exercise prices of the underlying awards and the quoted stock price of the Company's common stock as of the reporting date.

As of June 30, 2011, the total compensation cost related to unvested options not yet recognized in the financial statements is approximately $5,544, net of estimated forfeitures, and the weighted average period over which this amount is expected to be recognized is 1.6 years.

11. Comprehensive Loss

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

12. Stockholders' Equity

Changes in stockholders' equity for the six months ended June 30, 2011 and 2010 were as follows:

	For the Six Months Ended June 30,	
	2011	2010
Balance at December 31, 2010 and 2009	$ 50,544	$ 1,022
Net loss	(21,383)	(12,020)
Stock based compensation	1,326	938
Exercise of stock options	480	—
Change in unrealized loss on marketable securities	2	(6)
Issuance of common stock	60,960	22,628
Issuance of common stock under the Employee Stock Purchase Plan	75	50
Balance at June 30, 2011 and 2010	$ 92,004	$ 12,612

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

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we "believe," "expect," "anticipate," "plan," "target," "intend" and similar expressions should be considered forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including factors discussed in this section and elsewhere in this quarterly report on Form 10-Q, including those discussed in Item 1A of this report under the heading "Risk Factors," and the risks discussed in our other filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis, judgment, belief or expectation only as the date hereof. We assume no obligation to update these forward-looking statements to reflect events or circumstances that arise after the date hereof.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of 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 and the development of antibacterials for the treatment of resistant bacterial infections. We are currently focusing our efforts on developing HCV drug candidates for the treatment of chronic hepatitis C:

- ACH-1625, a protease inhibitor for the treatment of chronic HCV infection, currently being tested in an on-going phase IIa clinical trial;
- ACH-2684, a pangenotypic protease inhibitor for the treatment of chronic HCV infection, currently being tested in a phase I clinical trial; and
- a portfolio of NS5A inhibitors for the treatment of chronic HCV infection, including ACH-2928, currently being tested in a phase I clinical trial, and several additional NS5A inhibitors currently in preclinical development.

We also have developed ACH-1095, a NS4A antagonist for the treatment of chronic hepatitis C, to which Gilead Sciences, Inc., or Gilead, retains certain future development rights. We are not devoting significant resources at this time to the further development of ACH-1095. In addition, we have established a pipeline of certain 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 opthalmic infections, ACH-2881 for the treatment of serious resistant bacterial infections, including methicillin resistant staphylococcus aureus, and elvucitabine for the treatment of HIV infection.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of $239 million from inception through June 30, 2011 and had an accumulated deficit of $253 million at June 30, 2011, which includes preferred stock dividends recognized until our initial public offering in 2006. Our net losses were $21.4 million and $12.0 million for the six months ended June 30, 2011 and 2010, 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 one of our collaboration partners, Gilead.

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

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

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

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

- continue clinical testing of ACH-1625, ACH-2684 and ACH-2928; and
- identify and progress additional drug candidates.

In June 2011, at our annual meeting of stockholders, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation to increase the Company's authorized shares of common stock from 100,000,000 to 200,000,000 in order to give the Company greater flexibility in considering and planning for potential business needs.

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 collaboration with Gilead to develop compounds for use in treating chronic hepatitis C. During the six months ended June 30, 2011 and 2010, we recognized $121,000 and $117,000, respectively, under this collaboration agreement, all of which related to external costs billed by us to Gilead.

Upon initiating our collaboration with Gilead, 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 is being accounted for as a nonrefundable up-front fee recognized under the proportionate performance model. Revenue under the proportionate performance model is recognized as our effort under the collaboration is incurred. Payments made by us to Gilead in connection with this collaboration are recognized as a reduction of revenue. When our performance obligation is complete, we will recognize milestone payments, if any, when the corresponding milestone is achieved. We will recognize royalty payments, if any, upon product sales.

We did not recognize any revenue related to the amortization of deferred revenue during the six months ended June 30, 2011 and 2010, as we were unable to accurately estimate our total performance obligations under the Gilead collaboration. We will determine if we are able to estimate our remaining total performance obligations when and if a new lead compound under the collaboration is identified.

Through the completion of our performance obligations under the collaboration with Gilead, we expect to recognize the remaining $2.5 million of deferred revenue related to the amortization of the upfront, milestone and FTE payments received, offset by any payments we are obligated to make to Gilead in satisfaction of external costs paid by Gilead under our external cost-sharing arrangement. It is possible that we will recognize negative revenue in future periods based upon the timing of our performance under the collaboration and on the timing and magnitude of external costs borne by Gilead.

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:

- **ACH-1625, a Protease Inhibitor for Chronic HCV Infection.** We are developing ACH-1625, a protease inhibitor for the treatment of chronic HCV. We are currently conducting a phase IIa clinical trial in both the United States and Europe to assess the compound's safety, tolerability, pharmacokinetic properties and efficacy in HCV-infected subjects. In preclinical studies, ACH-1625 demonstrated strong potency, liver partitioning and a good safety profile. In phase Ia and phase Ib clinical trials, ACH-1625 was demonstrated to be safe and well-

tolerated at total daily doses ranging from 50mg to 2000mg. Further, ACH-1625 significantly reduced viral load in HCV patients by 3.40 log_{10} to 4.25 log_{10} at doses ranging from 200 to 600 mg twice daily and 400 and 600 mg once daily. Results from the first 28-day segment of the phase IIa trial demonstrated that 75-81% of patients receiving ACH-1625 in combination with pegylated interferon alfa-2a and ribavirin achieved rapid virologic response, or RVR, with a promising safety and tolerability profile. Viral load was reduced in HCV patients by 4.63 log_{10} to 4.96 log_{10} at doses ranging from 200 to 800 mg once daily. A second 12-week segment of this phase IIa trial is on-going.

- **ACH-2684, a Pangenotypic Protease Inhibitor for Chronic HCV Infection.** We are developing ACH-2684 for the treatment of chronic HCV infection. In preclinical studies, ACH-2684 has demonstrated excellent potency in the picomolar range, as well as good pharmacokinetic and safety profiles. The potency and virology profiles of ACH-2684 demonstrate that it effectively suppresses a broad range of natural variants of HCV, and may be effective in the prevention and treatment of emerging resistant variants. This compound also retains potent *in vitro* activity against all known HCV genotypes. The very high potency of ACH-2684 was achieved by designing the compound to optimize the way in which it binds with NS3 protease. In preclinical studies, ACH-2684 was effective in combination with other HCV inhibitors, and *in vitro* is synergistic with NS5B nucleoside polymerase inhibitors. We have initiated a phase I clinical trial for ACH-2684.
- **NS5A Inhibitors for Chronic HCV Infection.** We are progressing selected NS5A inhibitors for the treatment of chronic HCV infection, including ACH-2928, a lead compound in our portfolio of NS5A inhibitors, as well as ACH-3080, ACH-3102 and ACH-3107, preclinical candidates with improved virology profiles in the replicon assay. In early preclinical studies, these compounds demonstrate excellent potency against HCV RNA replication, as well as good pharmacokinetic and safety profiles. These compounds are highly active and potent against HCV genotypes 1a and 1b, as well as across other genotypes. We believe their high potency, in the picomolar range, and their favorable pharmacokinetic properties, strongly suggest once-daily dosing. Importantly, NS5A inhibitors are highly effective in combination with NS3 protease inhibitors, NS5B polymerase inhibitors, interferon and ribavirin. We have initiated a phase I clinical trial for ACH-2928. We will select an optimal NS5A inhibitor for clinical testing in a combination regimen based upon its virology and safety characteristics, and other business considerations.
- **Other drug candidates.** We have also established a pipeline of other product candidates for which we have or are currently seeking appropriate collaborative partners, but to which we are not devoting significant resources at this time: ACH-702 and ACH-2881 for drug resistant bacterial infections, elvucitabine for HIV infection, and ACH-1095 for HCV infection for which Gilead retains certain future development rights.

We intend to continue to focus on the discovery 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,	
	2011	2010
Clinical candidate direct external costs:	(in thousands)	
ACH-1625 (and related compounds)	$ 6,867	$ 2,667
ACH-2684 (and related compounds)	2,668	471
ACH-2928 (and related compounds)	1,586	—
Other	92	479
	11,213	3,617
Direct internal personnel costs	3,765	3,292
Sub-total direct costs	14,978	6,909
Indirect costs and overhead	1,984	1,929
Research and development tax credit	(73)	(65)
Total research and development	$ 16,889	$ 8,773

We are currently conducting a phase IIa clinical trial of ACH-1625 and phase I clinical trials of ACH-2684 and ACH-2928. We expect 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 program-specific expenses through commercialization. There exist numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will evolve and therefore impact our clinical development programs and plans over time.

General and Administrative

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

Critical Accounting Standards and Estimates

Preparation of our financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. A summary of our critical accounting estimates is included in Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2010. 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 2011, 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, 2011 and 2010

Revenue. Revenue recognized during the three months ended June 30, 2011 and 2010 was $56,000 and $187,000, respectively, and $121,000 and $261,000 for the six months ended June 30, 2011 and 2010, respectively. The decrease in revenue in 2011 is primarily related to the recognition of Small Business Innovation Research grant revenue during 2010.

Because we are currently unable to estimate our future performance obligations under our collaboration with Gilead, we have ceased recognizing revenue related to upfront, milestone and FTE payments previously received until we can reasonably estimate our total future performance obligations under the collaboration. We will determine if we are able to estimate our remaining future performance obligations when and if a new lead candidate under the collaboration is identified. Under the proportionate performance method, periodic revenue related to upfront license and milestone payments is recognized as the percentage of actual effort expended in that period to total effort expected for all of our performance obligations under the arrangement. Additionally, under the collaboration arrangement, external costs are shared by both parties and payments we make to Gilead are recognized as a reduction of revenue. Revenue for the three and six months ended June 30, 2011 and 2010 is comprised as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
	(in thousands)			(in thousands)		
Gilead collaboration revenue	$ 56	$ 43	13	$121	$117	$ 4
Grant revenue	—	144	(144)	—	144	(144)
Total revenue	$ 56	$ 187	(131)	$121	$261	$ (140)

Through the completion of our performance obligations under the collaboration with Gilead, we expect to recognize additional revenue of approximately $2.5 million, offset by any payments we are obligated to make to Gilead in satisfaction of external costs paid by Gilead under our external cost-sharing arrangement. It is possible that we will recognize negative revenue in future quarters based upon the timing of our performance under the collaboration and on the timing and magnitude of external costs borne by Gilead.

Research and Development Expenses. Research and development expenses were $8.9 million and $4.8 million for the three months ended June 30, 2011 and 2010, respectively, and $16.9 million and $8.8 million for the six months ended June 30, 2011 and 2010, respectively. The increase for the three and six months ended June 30, 2011 was primarily due to increased expenses related to clinical testing of ACH-1625 and ACH-2684, combined with increased preclinical costs for ACH-2684 and ACH-2928. We expect research and development expenses to remain consistent with 2011 levels during the remainder of the year, as we continue clinical testing of ACH-1625, ACH-2684 and ACH-2928. Research and development expenses for the three and six months ended June 30, 2011 and 2010 are comprised as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Personnel costs	$1,593	$1,410	$ 183	$ 3,220	$2,912	$ 308
Stock based compensation	277	188	89	543	378	165
Outsourced research and supplies	6,129	2,320	3,809	11,070	3,615	7,455
Professional and consulting fees	397	339	58	1,050	709	341
Facilities costs	460	517	(57)	933	1,117	(184)
Travel and other costs	80	75	5	146	107	39
Research and development tax credit	(40)	(35)	(5)	(73)	(65)	(8)
Total	$8,896	$4,814	$4,082	$16,889	$8,773	$8,116

General and Administrative Expenses. General and administrative expenses were $2.4 million and $1.7 million for the three months ended June 30, 2011 and 2010, respectively, and $4.7 million and $3.4 million for the six months ended June 30, 2011 and 2010, respectively. The increase for the three and six months ended June 30, 2011 was primarily due to an increase in professional and consulting fees including business development consulting fees, corporate legal fees, and directors' compensation. 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, 2011 and 2010 are comprised as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Personnel costs	$ 755	$ 596	$ 159	$1,520	$1,240	$ 280
Stock based compensation	401	279	122	783	560	223
Professional and consulting fees	688	356	332	1,255	654	601
Facilities costs	282	282	—	515	519	(4)
Travel and other costs	310	177	133	586	384	202
Total	$2,436	$1,690	$ 746	$4,659	$3,357	$1,302

Other Income (Expense). Interest income was $30,000 and $15,000 for the three months ended June 30, 2011 and 2010, respectively. The increase was primarily due to increased average cash balances. Interest expense was $4,000 and $82,000 for the three months ended June 30, 2011 and 2010, respectively. The decrease was primarily due to lower average debt facility balances outstanding in 2011.

Interest income was $70,000 and $25,000 for the six months ended June 30, 2011 and 2010, respectively. The increase was primarily due to increased average cash balances. Interest expense was $26,000 and $176,000 for the six months ended June 30, 2011 and 2010, respectively. The decrease was primarily due to lower average debt facility balances outstanding in 2011.

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 collaboration with Gilead. Through June 30, 2011, 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, $19.3 million from Gilead under our collaboration agreement and approximately $22.6 million under debt facilities. As of June 30, 2011, our debt balance due to borrowings was $438,000 with an interest rate of 6.79%.

We had $99.6 million and $55.2 million in cash, cash equivalents and marketable securities as of June 30, 2011 and December 31, 2010, respectively. We regularly review our investments and monitor the financial markets. As of June 30, 2011, 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 $16.4 million for the six months ended June 30, 2011 and was primarily attributable to our $21.4 million net loss, offset primarily by non-cash stock based compensation, combined with increases in accounts payable and accrued expenses. Cash used in operating activities was $11.5 million for the six months ended June 30, 2010 and was primarily attributable to our $12.0 million net loss combined with an increase in prepaid expense and a decrease in accrued expenses, offset primarily by non-cash charges related to depreciation, amortization and non-cash stock based compensation.

Cash provided by investing activities was $11.5 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. Cash used in investing activities was $5.5 million for the six months ended June 30, 2010 and was primarily attributable to the purchase of marketable securities.

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. Cash provided by financing activities was $21.5 million for the six months ended June 30, 2010 and was primarily attributable to $22.6 million in net proceeds from the sale of 11,816,250 shares of common stock in January and February 2010, offset by repayments of debt.

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 ACH-1625, ACH-2684 and ACH-2928; and
- identify and progress additional drug candidates.

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements through at least June 30, 2012. 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 ACH-1625, ACH-2684 and ACH-2928;
- our ability to enter into corporate collaborations for our HCV candidates and the terms and success of these collaborations;
- any partnership opportunities that may arise for elvucitabine, ACH-702 or ACH-2881 that we determine to pursue;
- 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.

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

In October 2009, an update was made to ASC 605, *Revenue Recognition,* which provides accounting principles and application guidance on how revenue arrangements with multiple deliverables should be separated and the consideration allocated. Assuming other criteria are met, this guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition. Allocation of consideration is now based on management's estimate of the selling price for an undelivered item where there is no other means to determine the fair value of that undelivered item. This update is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We adopted this standard as of January 1, 2011. There was no impact to our financial statements upon adoption of this standard, as there were no new or modified agreements.

In May 2011, the FASB issued ASU No. 2011-04 "Fair Value Measurement: Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs". The amendments clarify the FASB's intent about the application of existing fair value measurement and disclosure requirements and in some instances change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. Notable changes under the amended guidance include: (i) application of the highest and best use and valuation premise concepts solely for non-financial assets and liabilities; (ii) measuring the fair value of an instrument classified in a reporting entity's shareholders' equity; and (iii) disclosing quantitative information about unobservable inputs used in the fair value measurement within Level 3 of the fair value hierarchy. For public entities, the amendment is effective for interim and annual periods beginning after December 15, 2011. Early application is not permitted. We are currently evaluating the disclosure requirements related to providing quantitative information about unobservable inputs used to measure the fair value of its contingent consideration liability.

In June 2011, the FASB issued ASU No. 2011-05 "Comprehensive Income: Presentation of Comprehensive Income." Under the amendment, an entity will have 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, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does 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. We will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will not have any other effect on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. Our exposure to market risk is confined to our cash, cash equivalents and marketable securities. We regularly review our investments and monitor the financial markets. We invest in high-quality financial instruments, primarily money market funds, government sponsored bond obligations and government backed corporate debt securities, with the effective duration of the portfolio less than 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.

Capital Market Risk. We currently have no product revenues and depend on funds raised through other sources. One source of funding is through future 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, 2011. 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, 2011, 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, 2011 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 chronic HCV infection, including our protease inhibitors, ACH-1625 and ACH-2684 and our NS5A inhibitors, ACH-2928 and related compounds. 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 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;
- 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 ACH-1625, phase I clinical trials for ACH-2684 and ACH-2928 and late-stage preclinical assessment of additional NS5A inhibitors. 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 ACH-1625, ACH-2684 or ACH-2928 or the completed clinical trials for ACH-1625 may not be predictive of the results we may obtain in later stage trials.

We do not expect any of our drug candidates 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, 2011, our accumulated deficit was approximately $252.8 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 chronic HCV. Additionally, there may be competitive drugs currently under development of which we are not aware. We would expect our drug candidates to compete with the following approved drugs and drug candidates currently under development:

If approved, our protease inhibitors, ACH-1625 and ACH-2684, and our NS5A inhibitors, ACH-2928 and related compounds, would compete with drugs currently approved for the treatment of HCV, i.e., the interferon-alpha-based products from Roche (Pegasys and Roferon-A) or Merck (Intron-A or Peg-Intron), the ribavirin based products from Merck (Rebetrol), Roche (Copegus) or generic versions sold by various companies, as well as recently-approved protease inhibitors teleprevir (Incivek) by Vertex and boceprevir (Vicetrelis) 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 Human Genome Sciences' Albuferon, and with other products in development in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors, toll-like receptors and cyclophilin inhibitors also under development for the treatment of HCV by companies such as Abbott, Anadys, Astra-Zeneca, Avila Therapeutics, Boehringer Ingelheim, Bristol-Myers Squibb, Enanta, Gilead, GlaxoSmithKline, Human Genome Sciences, Idenix, Johnson & Johnson, Presidio, Medivir, Merck, Novartis, Pfizer, Pharmasset, 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.

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 and cash equivalents will be sufficient to support our current operating plan for at least the next 12 months. 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, ACH-1625 and ACH-2684, and our NS5A inhibitors, ACH-2928 and related compounds;
- our ability to enter into corporate collaborations for our HCV candidates and the terms and success of these collaborations;
- any partnership opportunities that may arise for elvucitabine, ACH-702 or ACH-2881 that we determine to pursue;
- 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, all of which remain outstanding. These financings substantially diluted our existing stockholders.

Stockholders will be further diluted if, and to the extent, any warrants are exercised. Debt financing, if available, may involve covenants that limit or restrict our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends, or may involve immediate repayment of the debt under certain circumstances. If we raise additional funds through collaborations, strategic alliances and licensing arrangements with third parties, we may 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 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.

Risks Related to the Development of Our Drug Candidates

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

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

- offer therapeutic or other improvement over existing, comparable drugs;
- be proven safe and effective in clinical trials;
- have the desired effects, or may include undesirable effects or may have other unexpected characteristics;
- meet applicable regulatory standards;
- be capable of being produced in commercial quantities at acceptable costs; or
- be successfully commercialized.

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

- regulators or Institutional Review Boards, or IRBs, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- 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 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, in connection with future HCV development guidelines recently circulated for comment, 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, ACH-1625 is being studied in combination with the current standard of care. Recently approved therapies, including teleprevir (Incivek) and boceprivir (Victrelis) could, in time, 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 ACH-1625, ACH-2684, ACH-2928, 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.

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 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.

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 ACH-1625 into longer term clinical trials in Phase IIa, we have established predetermined stopping rules, as well as a Data Safety Monitoring Board (DSMB) in order to monitor and ensure patient safety. The FDA has also required us to perform data analysis between patient cohorts in our phase I clinical trials of ACH-2684 and ACH-2928. Any interruption of these clinical trials, whether as a result of one of our drug candidates, of co-administration of the standard of care, 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.

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.

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 entered into arrangements with Gilead for the development and commercialization of certain of our HCV compounds involving NS4A antagonism, and with GCA Therapeutics, Ltd., or GCAT, for the development and commercialization of 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 other specific drug candidates and to jointly commercialize them if they are approved. 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, if at all. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. 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 elvucitabine or our antibacterial drug candidates, ACH-702 and ACH-2881, independently.

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.

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 intend to 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 plan to enter into arrangements with other companies for commercialization. For example, we have entered into an agreement with Gilead for the development and commercialization of certain of our HCV candidates involving NS4A antagonism. 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 (DAAs) 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 chronic HCV infection. 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 immunomodulatory therapy with pegylated interferon and ribavirin. Two DAAs developed by our competitors, teleprevir (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 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 the current standard of care (pegylated interferon and ribavirin), our inhibitors with the current standard of care plus another DAA, or our inhibitors with one or more DAAs without concomitant interferon or 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. 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 chronic HCV infection 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 ACH-1625, ACH-2684, ACH-2928, 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 commercial launch of teleprevir (Incivek) by Vertex and boceprevir (Victrelis) by Merck, which were recently approved by the FDA;
- the demonstrated clinical safety and efficacy of our product candidates compared to other drugs;
- the cost-effectiveness of our product candidates;
- the availability of reimbursement from managed care plans, the government and other third-party payors;
- 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; and
- the effectiveness of marketing and distribution support.

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

If we are unable to meet the operational, legal and financial challenges that we encounter with international partnerships, we may not be able to grow our business.

We entered into an agreement with GCAT which grants GCAT, through its Chinese joint venture with Tianjing Institute of Pharmaceutical Research, the right to clinically develop and commercialize elvucitabine in mainland China, Hong Kong and Taiwan. Conducting business in China exposes us to a variety of risks and uncertainties that are unique to China. The economy of China has been transitioning from a planned economy to a market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Efforts by the Chinese government to slow the pace of growth of the Chinese economy could result in interruptions of our development and commercialization efforts in China. In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. Accordingly, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our development and commercialization efforts in China could be materially harmed by any changes in the political, legal or economic climate in China or the inability to enforce applicable Chinese laws and regulations. If such commercialization efforts in China are materially harmed, our collaboration partner may not be able to develop and commercialize elvucitabine in China and our elvucitabine business may not grow.

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 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.

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 Sciences 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 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.

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

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

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

In addition, under the Bayh-Dole Act, the federal government has certain rights to the technology licensed to us from Emory University.

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 BMS, 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 Vion Pharmaceuticals 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. Pursuant to our license agreement with Emory University and our research collaboration and license agreement with Gilead Sciences, Emory and Gilead have the primary right, but not an obligation, to bring actions against an infringing third party. However, if Gilead or Emory elects not to bring an action, we may bring an action against the infringing party.

Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Because of the relative weakness of the Chinese legal system in general, and 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.

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, 2011, 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 56% 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.

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, 2011, 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 planned clinical trials of our protease inhibitors, ACH-1625 and ACH-2684 and our NS5A inhibitors, ACH-2928 and related compounds;
- the entry into, modification of, or termination of key agreements, or any new collaboration agreement we may enter;
- 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 results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- the launch of drugs by others that would compete with our drug candidates;
- the failure or discontinuation of any of our research programs;
- issues in manufacturing our drug candidates or any approved products;
- the introduction of technological innovations or new commercial products by us or our competitors;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- future sales of our common stock;
- changes in the structure of health care payment systems;
- period-to-period fluctuations in our financial results; and

- low trading volume of our common stock.

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

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

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

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

Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

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

31.1	Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.
32.2	Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Calculation Linkbase Document*
101.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, 2011 and December 31, 2010 (unaudited), (ii) Statements of Operations for the three and six months ended June 30, 2011 and 2010 (unaudited), (iii) Statements of Cash Flows for the six months ended June 30, 2011 and 2010 (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.

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, 2011

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

Date: August 8, 2011

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

EXHIBIT INDEX

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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.

Exhibit 31.1

Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Michael D. Kishbauch, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control and financial reporting.

/S/ MICHAEL D. KISHBAUCH
Michael D. Kishbauch
Chief Executive Officer

Dated: August 8, 2011

Exhibit 31.2

Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Mary Kay Fenton certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control and financial reporting.

/S/ MARY KAY FENTON
Mary Kay Fenton
Chief Financial Officer

Date: August 8, 2011

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc. (the "Company") for the quarter ended June 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael D. Kishbauch, President and Chief Executive Officer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 8, 2011

/s/ Michael D. Kishbauch
Michael D. Kishbauch
President and Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc. (the "Company") for the quarter ended June 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mary Kay Fenton, Chief Financial Officer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 8, 2011

/s/ Mary Kay Fenton
Mary Kay Fenton
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.